

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION**

UNITED STATES OF AMERICA and	:	
THE STATES OF CALIFORNIA and	:	
ILLINOIS, EX REL. SCARLETT LUTZ and	:	CA NO.: 9:14-CV-3699-RMG
KAYLA WEBSTER,	:	HON. RICHARD M. GERGEL
	:	
Plaintiffs/Relators,	:	
v.	:	
	:	FOURTH AMENDED
LABORATORY CORPORATION OF	:	<i>QUI TAM</i> COMPLAINT
AMERICA HOLDINGS,	:	
	:	JURY TRIAL DEMANDED
Defendant.	:	
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FOURTH AMENDED *QUI TAM* COMPLAINT

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offers of illegal inducements to physicians and the referral of patients by physicians to HDL and Singulex labs.

Qui Tam Plaintiffs (“Relators”) Lutz and Webster, both residents of South Carolina, through their legal counsel, Pietragallo Gordon Alfano Bosick & Raspanti, LLP and Winston & Strawn, LLP, bring this action on their own behalf, and on behalf of the United States of America and the States of California and Illinois (hereafter “the Government”).

1. This is an action to recover monetary damages and civil penalties on behalf of the United States of America and the States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used, or presented by Defendant LabCorp and third parties HDL and Singulex, in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*, as amended (“the federal FCA”). This action also arises under the CIFPA and ILCFPA, private insurance *qui tam* statutes in the States of California and Illinois, respectively, where LabCorp did and continues to do extensive business.

2. During the relevant time period,¹ Defendant LabCorp, and third parties HDL and Singulex, were nationwide providers of clinical laboratory testing services. Many of the patients who received their services were beneficiaries of myriad Government programs, including, but not limited to, Medicare, TRICARE/CHAMPUS, numerous Medicaid programs, and other Government-funded healthcare programs. A significant number of patients receiving these services were insured by myriad private insurers, including patients who are residents of California and/or Illinois.

3. The unlawful scheme was wide-reaching and national in scope, but straightforward. HDL and Singulex offered cash remuneration to physicians to induce them to refer patients to

¹ Unless otherwise provided, the relevant time period is early 2010 to at least mid-2014.

HDL and Singulex for laboratory testing related to high cholesterol and predicting risk factors for coronary disease. HDL offered physicians \$20 per patient referral. Singulex offered physicians \$10 for each patient referred. Both HDL and Singulex attempted to disguise these illegal remunerations through sham “processing fee” arrangements with referring physicians. A physician who referred a patient to both HDL and Singulex received a total of \$30 in “processing fees” each time the patient was tested.

4. LabCorp, among other things, provides phlebotomy services, which refers to the drawing or removing blood from a patient’s circulatory system through a cut (incision) or puncture (“venipuncture”) in order to obtain a blood sample that can be used for analysis or diagnosis. LabCorp’s phlebotomy services include both the venipuncture and processing and handling of the blood sample so that it can be used for testing.

5. Defendant LabCorp participated fully and profitably in the fraudulent scheme by providing free blood draw and processing services to physicians for patients referred to HDL and Singulex. In particular, LabCorp technicians provided these referring physicians with free services: drawing blood from patients, processing it, and packaging individual blood samples in preparation for shipment to HDL or Singulex. In doing so, LabCorp conspired with HDL and Singulex and caused the submission of false claims tainted by HDL and Singulex kickbacks. LabCorp also submitted or caused the submission of false claims for LabCorp tests. In exchange for LabCorp performing these free blood drawing and processing services, physicians who received kickbacks from HDL and Singulex also regularly ordered tests from LabCorp. Many of these LabCorp tests were medically unnecessary and even duplicative of HDL tests.

6. In exchange for these inducements, from early 2010 through at least June 2014, physicians referred patients to HDL and Singulex, and physicians referred and continue to refer

patients to LabCorp.

7. One purpose of the illegal inducements offered by Defendant LabCorp and third parties HDL and Singulex is to obtain and maintain lucrative referrals from targeted physicians. Therefore, all claims submitted to Government healthcare programs and/or to private insurers in California and Illinois by HDL, Singulex, and LabCorp that were tainted by the fraudulent kickback scheme were false claims.

8. Defendant LabCorp and third parties HDL and Singulex violated the federal FCA by submitting or causing the submission of false claims for laboratory testing tainted by their fraudulent conduct, and by creating false or fraudulent records material to false claims.

9. Defendant LabCorp's kickback scheme also violated Section 1871.7(a) of the CIFPA, Cal. Ins. Code 1871.7(a), and Section 92/5(a) of the ILCFPA, 740 Ill. Comp. Stat. § 92/5(a), because LabCorp entered into illegal arrangements with physicians that provided financial incentives for the use of their laboratory services, resulting in medically unnecessary testing that is then billed to private insurers.

10. In addition, Defendant LabCorp has violated the federal FCA by conspiring with HDL and Singulex to submit and/or to cause the submission of false claims by HDL and Singulex for these illegally induced laboratory tests to state healthcare programs, including the federally-funded Medicaid program. Defendant LabCorp also conspired to create and/or use false records material to the false or fraudulent claims for laboratory testing services submitted by Defendant LabCorp and third parties HDL and Singulex to federally-funded state health care programs, including Medicaid.

11. Having submitted, and/or caused the submission of, these false claims to federally-funded health care programs, Defendant LabCorp violated the federal FCA by failing to return to

federally-funded Government healthcare programs known overpayments associated with illegally obtained federal funds. LabCorp had knowledge of the falsity of its claims from at least early 2010.

12. The national scheme of LabCorp, HDL, and Singulex caused further damage to Government healthcare programs, in addition to the reimbursements for the illegally induced and, in many cases, medically unnecessary tests themselves. As alleged below, this scheme caused beneficiaries of Government healthcare programs and private insurance plans in California and Illinois to receive other unnecessary healthcare, including follow-up physician visits, follow-up testing, and unnecessary medications related to the illegal referrals to Defendant LabCorp, as well as third parties HDL and Singulex.

13. During the relevant time period, LabCorp, HDL, and Singulex's operations extended across the United States, and their kickback scheme was national in scope.

14. Relators have observed firsthand the corporate scheme employed by LabCorp, HDL, and Singulex operating in the Florence, South Carolina office of Lloyd Miller, MD, a customer of LabCorp, HDL and Singulex.

15. Since at least April 2010, Defendant LabCorp had direct and constructive knowledge of kickbacks provided to its customers by HDL and Singulex. LabCorp continued to document this knowledge throughout the relevant time period.

16. From at least April 2012 through at least February 2014, LabCorp directed the drafting of requests for a fraud alert from the Office of Inspector General, U.S. Department of Health & Human Services ("OIG fraud alert"). LabCorp submitted these requests in February 2013 and February 2014. In its requests to OIG, LabCorp identified HDL's and Singulex's conduct in providing inducements, including payment of above-market draw fees, as fraud. During this same time, LabCorp continued to document its physician customers' receipt of inducements from

HDL and Singulex. However, LabCorp never communicated its own involvement in providing blood draw and processing services for the tainted HDL or Singulex tests to the federal Government or to private health care insurers, including those covering insureds located in California and Illinois.

17. However, LabCorp concealed from both the federal Government and private insurers, including those located in California and Illinois, both its participation in the HDL and Singulex kickback scheme, and the inducements that LabCorp offered and/or provided to referring physicians.

18. In spite of its knowledge, from early 2010 until at least mid-2014, LabCorp knowingly provided free phlebotomy services to its physician customers for blood samples referred to HDL and Singulex for testing. LabCorp effectively ensured the physical delivery of patient referrals to HDL and Singulex, which triggered the physicians' receipt of kickback payments from HDL and Singulex.

19. The claims against Defendant for violations of the federal FCA are based upon false certifications and false or fraudulent claims that Defendant presented or caused to be presented to Government healthcare programs for laboratory testing services referred by physicians with whom Defendant had illegal financial relationships under the AKS.

20. The resulting claims for laboratory tests which were tainted by inducements offered to, or accepted by, referring physicians and submitted by HDL and Singulex to federally funded healthcare programs and state healthcare insurers in California and Illinois were false under both the federal FCA and the insurance fraud statutes of California and Illinois.

21. LabCorp physically participated in the payment of inducements offered by HDL and Singulex. LabCorp's conduct in participating in the delivery of blood samples to HDL and

Singulex triggered the kickback payments by Singulex and HDL to referring physicians. LabCorp's conduct, therefore, caused the submission of false claims by HDL and Singulex to Government healthcare programs and to private insurers in California and Illinois.

22. LabCorp also provided its own inducements to its physician and physician practice customers in the form of free blood draw and processing services in violation of the federal AKS and California and Illinois law. LabCorp offered and/or provided these inducements in order to remain competitive by gaining new contracts or maintaining or expanding its existing contracts with physicians or physician practices. Therefore, LabCorp's conduct resulted in the submission of false claims for patients referred to LabCorp by physicians who had received LabCorp's own inducements.

II. JURISDICTION AND VENUE

23. This action arises under the laws of the United States of America to redress violations of the federal FCA, 31 U.S.C. § 3729 *et seq.* Defendant LabCorp does business in the District of South Carolina and throughout the United States. The acts proscribed by 31 U.S.C. § 3729(a) and described in this *Qui Tam* Complaint occurred in the District of South Carolina and elsewhere in the United States.

24. Subject matter jurisdiction over this *qui tam* action is conferred by 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730(b). Relator Lutz and Relator Webster are each an "original source" and otherwise authorized to maintain this action in the name of the United States and as contemplated by the FCA, 31 U.S.C. §§ 3729-33, and in the name of the Plaintiff states of California and Illinois.

25. Relators have made all of the necessary voluntary disclosures to the Government prior to the filing of this lawsuit and have filed all documents necessary with the United States Government as required by 31 U.S.C. § 3730(b)(2). Relators have also made all voluntary

disclosures to the States of California and Illinois prior to the filing of this lawsuit and have filed all necessary documents as required by the CIFPA and ILCFPA.

26. There has been no public disclosure of the “allegations or transactions” in this Complaint under Section 3730(e) of the federal FCA. The specific facts, circumstances, and allegations of Defendant LabCorp’s violations of the federal FCA and the CIFPA and ILCFPA have not been publicly disclosed in a civil suit or administrative civil money penalty proceeding in which the Government is already a party.

27. Relators, moreover, would qualify as and are an “original source” of the allegations in this *Qui Tam* Complaint under 31 U.S.C. § 3730(e) of the federal FCA, and under the CIFPA and ILCFPA even had such a public disclosure occurred.

28. The Court has personal jurisdiction over Defendant because 31 U.S.C. § 3732(a) authorizes nationwide service of process, and because Defendant has minimum contacts with the United States, can be found in, and transacts or has transacted business in the District of South Carolina.

29. Defendant regularly performs healthcare services in and submits or causes the submission of thousands of claims for payment to federal and state health care programs, including, but not limited to, Medicare and Medicaid, and accordingly, is subject to the jurisdiction of this Court.

30. Venue lies under 28 U.S.C. § 1391(b), (c) and 31 U.S.C. § 3732(a) because the District of South Carolina is a district in which Defendant can be found or transacts business, and an act proscribed by 31 U.S.C. § 3729 occurred within this district.

31. The Court has supplemental jurisdiction, pursuant to 28 U.S.C. § 1367, over the causes of action brought under the laws of the States of California and Illinois for the recovery of

funds paid by a private insurer located in these states because these arise from the same operative facts forming the basis of the action brought under 31 U.S.C. § 3730.

III. PROCEDURAL HISTORY

32. On February 6, 2013, *Qui Tam* Relators filed their Original Complaint against Defendant, under seal in the U.S. District Court for the Western District of North Carolina.

33. Pursuant to this Court's Order, and the federal False Claims Act, 31 U.S.C. § 3730(b), this case has remained under seal while the United States investigated the allegations in Relators' Complaint.

34. In the fall of 2013, in the midst of the various Governments' investigations, the U.S. Department of Justice ("DOJ") requested that Relators consent to the United States' request to transfer this matter to the District of South Carolina, where Relators reside.

35. Pursuant to the request by the United States, on January 24, 2014, Relators and the United States filed a joint motion to transfer this action to the District of South Carolina.

36. On January 27, 2014, the U.S. District Court for the Western District of North Carolina granted the United States' and Relators' request pursuant to 28 U.S.C. § 1404(a) and entered an Order granting the motion to transfer this case, including the Complaint and all pleadings, and directing that all pleadings and matters filed remain under seal.

37. On September 18, 2014, this Court severed the allegations against Defendant LabCorp and directed that Relators file a Severed Second Amended *Qui Tam* Complaint against Defendant LabCorp. On September 26, 2014, Relators filed a Severed Second Amended *Qui Tam* Complaint against Defendant LabCorp.

38. The effect of the Second Severed Amended *Qui Tam* Complaint was to allow the Government to continue to investigate the claims against LabCorp while the Government intervened in and resolved or litigated Relators' claims against other participants in the scheme,

including HDL, Singulex, LaTonya Mallory, BlueWave, Floyd Calhoun Dent, and Robert Bradford Johnson.

39. On April 9, 2015, the DOJ announced that it had reached settlements with HDL and Singulex. Both companies agreed to resolve allegations, including those brought by Relators Lutz and Webster, that they violated the federal False Claims Act by providing remuneration to physicians in exchange for patient referrals and billing federal health care programs for medically unnecessary testing. Under the settlements, which were both resolutions based on the Defendant's "ability to pay," HDL agreed to pay \$47 million and Singulex agreed to pay \$1.5 million.

40. On June 7, 2015, HDL sought relief under the provisions of Chapter 11 of the United States Bankruptcy Code. Before filing for bankruptcy, HDL had paid only a fraction of the settlement funds owed to the Government.

41. At the time that these settlements were reached, the Government also intervened in Lutz and Webster's similar allegations against HDL and Singulex's national marketing company, BlueWave Healthcare Consultants Inc., and its owners, Dent and Johnson, as well as HDL's former CEO and co-founder, Mallory.

42. On September 23, 2015, Relators filed a Severed Third Amended *Qui Tam* Complaint against Defendant LabCorp in which Relators cured a pleading issue involving the improper omission of some of the then-Plaintiff states.

43. The case against BlueWave, Dent, Johnson, and Mallory proceeded through nearly two years of motion and discovery practice supervised by this Court.

44. On January 31, 2018, after a two-week trial, the South Carolina jury found that Mallory, Dent, and Johnson had violated the federal FCA by paying remuneration to physicians in exchange for patient referrals, in violation of the federal AKS. Mallory, Dent, and Johnson were

found to have caused HDL (and in the case of Dent and Johnson, to have caused Singulex) to submit false claims to federal health care programs. The three were found liable for \$50 million in damages owed to the federal Government for defrauding Medicare and Tricare.

45. On May 23, 2018, after denying the Defendants' requests for a new trial, the U.S. District Court for the District of South Carolina entered judgment for the United States, including statutory penalties, in the amounts of \$111,109,655.30 against Defendants Mallory, Dent and Johnson. The Court also entered a judgment against Dent and Johnson for an additional \$3,039,006.56 for false Singulex claims that were paid by federal healthcare programs. Johnson has since filed for bankruptcy.

46. While the case against Mallory, Dent, Johnson, and Bluewave was being litigated, this severed matter against LabCorp remained under seal and was actively investigated by the U.S. Attorney's Office in Columbia, South Carolina, Main Justice in Washington, D.C., and the California Department of Insurance. The Government has declined to intervene in this matter at this time. The Government has not moved to dismiss the Relators' Complaint. The Government's decision not to intervene is unrelated to its assessment of the merits of the Relators' allegations.

IV. THE PARTIES

A. Relators Lutz and Webster

47. *Qui Tam* Relator Scarlett Lutz ("Relator Lutz") is an individual residing in Florence, South Carolina.

48. Relator Lutz is the owner and operator of Palmetto Billing Services, 900 W. Evans Street, Florence, South Carolina 29501.

49. From March of 2011 until September of 2011, Relator Lutz provided billing services to Dr. Lloyd Miller, MD ("Dr. Miller"), a primary care physician practice in Florence, South Carolina.

50. During this time, Relator Lutz learned of HDL and Singulex's efforts to provide inducements to physicians and Dr. Miller's fraudulent conduct, which resulted in false billings to Government healthcare programs and private insurers for patients referred to HDL and Singulex, and related claims submitted by LabCorp for clinical laboratory testing.

51. *Qui Tam* Relator Kayla Webster, RN ("Relator Webster") is an individual residing in Timmonsville, South Carolina.

52. Relator Webster received a B.S. in Nursing from Francis Marion University in Florence, South Carolina in May 2008. Since that same time, Relator has been employed in South Carolina as a registered nurse.

53. Relator Webster has worked as a registered nurse for Comfort Keepers, a home health agency in Florence, South Carolina. In that capacity, she performs home visits and patient assessments.

54. From her graduation from college in 2008 until late July 2013, Relator Webster's main employment was as the Nursing Supervisor for Dr. Miller. In that capacity, Relator Webster interacted with numerous patients on a daily basis, performed clinical services, including triage, provided assistance with prescription medications, and observed Dr. Miller refer patients for clinical laboratory testing to be performed by LabCorp, HDL, and Singulex. Relator Webster also reviewed patient lab test results (including HDL and Singulex, and LabCorp). Relator Webster also regularly interacted with Government healthcare programs and private insurers on a variety of issues, including prior authorizations.

55. Through her experience as Nursing Supervisor in Dr. Miller's office, Relator Webster has direct and independent knowledge of the LabCorp, HDL, and Singulex marketing efforts and practices. She also has knowledge of inducements offered by HDL, Singulex, and

LabCorp to referring physicians, as well as Dr. Miller's practices with regard to patient referrals and patient blood draws for clinical laboratory testing.

56. During the relevant time period, Relators discussed their respective and collective knowledge regarding efforts by LabCorp, HDL, and Singulex to provide inducements to physicians, including Dr. Miller, all of which resulted in false billings to Government healthcare programs and private insurers for patients referred to LabCorp, HDL and/or Singulex for clinical laboratory testing

57. Relators have direct and independent knowledge of factual allegations contained in this *Qui Tam* Complaint and each of them brings this action as an "original source," as that term is defined by the FCA.

B. Defendant LabCorp

58. Defendant LabCorp is a Delaware for-profit corporation with a principal place of business located at 358 S. Main Street, Burlington, North Carolina 27215. LabCorp is a publicly traded company, which is listed on the NYSE as LH.

59. LabCorp is one of the largest provider of clinical laboratory services in the United States. According to its Security and Exchange Commission ("SEC") filings, LabCorp reported revenue of \$10.2 billion in fiscal year 2017, an increase of 8.2 percent compared to the previous fiscal year. Since 2010, when the scheme to induce referring physicians began, LabCorp has nearly doubled its reported net revenues of \$5 billion in 2010, and more than \$5.5 billion in 2011.

60. During the relevant time period, LabCorp operated through a number of geographic divisions, including: the Mid-Atlantic (at relevant times also called "Atlantic," which included South Carolina, North Carolina, and Virginia); Southeast (which included Georgia, Alabama, Mississippi, Tennessee, and Florida), North Central (which included Illinois, Indiana, Kentucky, Michigan, Ohio, West Virginia, and Wisconsin), Mid-America (which included Texas, Arizona, Colorado, New

Mexico, Louisiana, Arkansas, Oklahoma, Kansas, Missouri, Iowa, Minnesota, North Dakota, South Dakota), West (which included California, Oregon, Washington, and Idaho); and Northeast (which included Maryland, Delaware, New Jersey, Pennsylvania, New York, Connecticut, Rhode Island, Massachusetts, New Hampshire, Vermont, and Maine).

61. LabCorp transacts business throughout the United States and has extensive business contacts within the District of South Carolina.

62. LabCorp's President and Chief Executive Officer is David P. ("Dave") King. He joined the company in September 2001 as Senior Vice President, General Counsel, and Chief Compliance Officer. From January 2004 to December 2005, King acted as LabCorp's Executive Vice President of Strategic Planning and Corporate Development. Thereafter, from December 2005 to January 2007, he served as Executive Vice President ("EVP") and Chief Operating Officer ("COO").

63. CEO King has led LabCorp since January 2007, when he became President and Chief Executive Officer. Since May 2009, King has served as LabCorp's Chairman of the Board, President, and Chief Executive Officer. Before arriving at LabCorp, King had practiced for 17 years, both in private practice and with the DOJ. Among other board memberships, he also sits on the Board of the American Clinical Laboratory Association.

64. According to the company website, as a result of his long tenure and varied roles, "King has a deep understanding of the clinical laboratory industry, business strategy, sales and marketing and executive management of the Company and its operations." Relators believe this is an accurate statement.

65. In November 2006, while King was an EVP and COO at LabCorp, United Healthcare ("UHC"), an insurer based in Minnetonka, Minnesota, announced that it had awarded a ten-year exclusive service contract to LabCorp, effective January 2007. Under the terms of the agreement,

LabCorp became UHC's exclusive national laboratory and was charged with regional and local laboratory providers to develop and manage for UHC a series of laboratory networks in selected regions of the country. At the time, UHC provided health plan coverage (including HMO, POS, PPO, and indemnity plans) to a total of about 28 million members, which equated to roughly one out of every 12 people in the United States.

66. At the time, LabCorp expected to gain more than \$3 billion from UHC over the ten-year contract. LabCorp's then-COO, King, was charged with preparing LabCorp to take on the lucrative UHC contract, which included adding several hundred patient service centers ("PSCs") and hiring additional personnel, particularly in phlebotomy, logistics, and sales.

67. For his efforts, LabCorp is reported to have paid King \$11.6 million in 2017, an increase from \$10.8 million in 2016. On May 23, 2018, King is believed to have earned more than \$4.52 million from sales of LabCorp stock options. King owns more than 221,500 shares of LabCorp stock, currently worth an estimated \$40.3 million.

68. Throughout the relevant time period and with CEO King's knowledge and involvement, LabCorp engaged in two seemingly inconsistent courses of conduct. Through its top executives, the company feigned efforts to stop referrals to HDL and Singulex. LabCorp created the impression with private insurers (some of whom administered Medicare managed care plans), including UHC, that it was cooperating with their efforts to reverse the increasing flood of referrals to HDL and Singulex, which LabCorp knew were fueled by illegal kickbacks to physicians. LabCorp even went through the motions of obtaining an OIG fraud alert against HDL and Singulex.

69. At the same time, and as explained below, LabCorp executives at the highest levels (including CEO King and the company's executive vice presidents) actively pursued increasingly

lucrative business relationships with both HDL and Singulex. The self-contradicting conduct was indicative of LabCorp's knowledge of the illegality of the scheme.

70. LabCorp's mid-level executives and managers engaged in similarly inconsistent conduct: while recognizing that referrals by physicians receiving cash inducements from HDL and Singulex in violation of the AKS, they ignored LabCorp's written compliance policies to gain or maintain these lucrative physician accounts, as measured by their "estimated monthly value" ("EMV") of their referrals to LabCorp.

71. LabCorp's executives, managers, and employees throughout the United States took part in this nationwide fraud scheme. During the relevant time period, LabCorp provided phlebotomy services through both in-office phlebotomists ("IOPs") and phlebotomy service centers ("PSCs") that served nearby physician offices, including within the district. For example, LabCorp placed a phlebotomist in Dr. Miller's office in Florence, South Carolina.

72. LabCorp also performs testing services at various locations throughout the country, including their facility in Florence, South Carolina, which has a National Provider Identifier ("NPI") of 1750366753.

73. When LabCorp-paid phlebotomists perform blood draw and processing services, whether an IOP or a PSC, they use a requisition form which instructs the phlebotomist on the tests for which to draw and process blood specimens. For example, in Dr. Miller's office, the LabCorp phlebotomist received laboratory testing requisitions which indicated that she should draw and process blood specimens for labs including LabCorp, HDL, and Singulex.

74. At all times relevant to this matter, LabCorp phlebotomists communicated the number of blood draws (accessions) performed on a daily, weekly, and monthly basis. They also communicated to LabCorp when they drew blood for "non-LabCorp" tests.

75. When LabCorp performs testing services, one of the company's national testing facilities issues a report detailing the test results. LabCorp test results are issued in keeping with company-wide reporting formats and standards developed by LabCorp's corporate leaders. LabCorp transmits its test reports from LabCorp's testing facility to the referring physician's office, either through the mail or electronically,

76. Relators have reviewed test results for beneficiaries of Government healthcare programs, including Medicare and TRICARE, which were issued by LabCorp's national testing facilities according to its corporate standards. Some of these reports contained the notation: "Draw Fee to HDL." This is further evidence of LabCorp's knowledge of and involvement in the scheme with HDL (and Singulex) related to pay inducements to referring physicians (including LabCorp customers) in the form of above market "draw fees" or "process and handling" ("P&H") fees.

77. LabCorp calls its sales representatives "Key Account Executives" ("KAEs"). According to LabCorp job placement advertisements, KAEs are "outside field representative[s]" who "educate, instruct, and up sell [sic] all assigned and newly generated accounts in a predetermined geographic territory and enable the company to maximize and maintain the volume of business these accounts may produce." In addition, KAEs provide LabCorp customers with "ongoing service and problem solving." LabCorp KAEs retain and grow existing and new accounts and also provide ongoing customer service.

78. LabCorp provides laboratory testing for hundreds of thousands of South Carolina Medicaid recipients, some of whom are dual-eligible Medicare program beneficiaries.

79. Since at least 2000, LabCorp has served as a preferred provider for laboratory services for TRICARE beneficiaries including the TRICARE Mid-Atlantic region. TRICARE is the Department of Defense program that provides health care services to eligible military personnel and

their families. As of 2011, LabCorp was one of the two primary laboratory service providers for Humana Military Healthcare Services, Inc. (“Humana Military”), a provider of healthcare services for service members and their families in the TRICARE East region.

80. LabCorp does business with a number of commercial insurance providers in California including, but not limited to, Aetna, Blue Cross Blue Shield (“BCBS”), Cigna, Humana, Kaiser Permanente, and UHC. In Illinois, LabCorp does business with many commercial health insurance providers, including, but not limited to, Aetna, BCBS, Cigna, and Humana.

V. THIRD-PARTIES HDL AND SINGULEX

A. Health Diagnostic Laboratory, Inc. (“HDL”)

81. HDL was a Virginia for-profit corporation with a principal place of business at 737 N. 5th Street, Suite 103, Richmond, Virginia 23219. HDL was one of the leading providers in the United States of clinical laboratory testing for risk factors and biomarkers for cardiovascular and related diseases.

82. HDL, a privately held company, was formed in November of 2008. HDL started testing operations in November 2009. During the first quarter of 2010, HDL processed approximately 150 samples a day. By the end of 2011, HDL was running tests on about 2,700 samples daily.

83. As President and CEO, Mallory created and implemented HDL’s practice of paying sham processing and handling fees to physicians who referred blood samples to HDL for testing. Relator Lutz observed that Mallory personally signed the checks paid to referring physicians in exchange for the blood specimens they sent to HDL. During her tenure at HDL, Mallory received millions of dollars in salary, bonuses, and tax distributions.

84. As of the filing of Relators’ *Qui Tam* Complaint in February 2013, HDL served approximately 10,000 physicians and one million patients. HDL’s explosive growth was also illustrated through the size of its workforce. HDL transitioned from just a handful of employees in

2009 to nearly 900 employees at its apex in early 2014.

85. HDL transacted business in 45 states throughout the United States, including within South Carolina. HDL derived a significant portion of its revenues from Medicare and Medicaid reimbursements. Its NPI was 1629209853. HDL also derived substantial revenues from private insurers, including private healthcare insurers in California and Illinois.

86. As recited herein, on April 9, 2015, the Department of Justice announced that HDL and Singulex had entered into ability-to-pay settlements of \$47 million and \$1.5 million, respectively. Claims brought to the Government by Relators Lutz and Webster were included in those settlements.

87. On June 7, 2015, HDL filed a voluntary petition for liquidation under Chapter 11 of the U.S. Bankruptcy Code in the U.S. Bankruptcy Court for the Eastern District of Virginia. That matter continues in Richmond, Virginia under the supervision of a federal judge.

1. HDL Testing for Risk Factors for Cardiovascular Disease

88. HDL claimed that its clinical laboratory testing services identified factors contributing to cardiovascular disease, provided a basis for effective treatment, and allowed physicians to more effectively manage their patients. As an added value, HDL provided patients with a personalized overview of their risk factors and optional counseling from expert health coaches at no additional cost to the patient or their physician.

89. The relevant tests included in HDL's baseline testing panel, the relevant CPT codes and the Medicare reimbursement rates for 2012 were as follows:

CPT CODE	TEST	SOUTH CAROLINA MEDICARE REIMBURSEMENT RATE	NORTH CAROLINA MEDICARE REIMBURSEMENT RATE
80061	ApoB	\$13.88	\$18.97

83876	MPO (Myeloperoxidase)	\$48.08	\$48.08
83704	LDL-P	\$44.69	\$44.69
83704	HDL-P	-	-
83700	sdLDL	\$15.95	\$15.95
82541	Omega 3	\$25.57	\$25.57
82172	Apo A-1	\$15.28	\$21.95
83520	Galectin 3	\$18.34	\$18.34
82664	HDL 2 (subclass)	\$8.43	\$48.66
83695	Lp(a) mass w/reflex to Lp(a) cholesterol	\$18.34	\$18.34
83891*, 83892, 83896, 83903, 83908, 83912*	Apo E Genotype	\$5.68, \$5.68, \$5.68, \$23.74, \$23.74, \$5.68	\$5.68, \$5.68, \$5.68, \$5.84, \$5.84, \$5.68
83891, 83892, 83896, 83903, 83908, 83912	Factor V Leiden	\$5.68, \$5.68, \$5.68, \$23.74, \$23.74, \$5.68	\$5.68, \$5.68, \$5.68, \$5.84, \$5.84, \$5.68
83891, 83892, 83896, 83903, 83908, 83912	Prothrombin	\$5.68, \$5.68, \$5.68, \$23.74, \$23.74, \$5.68	\$5.68, \$5.68, \$5.68, \$5.84, \$5.84, \$5.68
83891, 83892, 83896, 83903, 83908, 83912	Cyp2C19	\$5.68, \$5.68, \$5.68, \$23.74, \$23.74, \$5.68	\$5.68, \$5.68, \$5.68, \$5.84, \$5.84, \$5.68
83698	Lp-PLA2	\$48.08	\$48.08
86141	hs-CRP	\$18.34	\$18.34
85384	Fibronogen	\$11.09	\$12.03
82726	FFA/NEFA	\$25.57	\$25.57
83880	NT-proBNP	\$48.08	\$48.08
83525	Insulin	\$16.19	\$16.19
82607	Vitamin B-12	\$21.35	\$21.35
82747	RBC Folate	\$24.53	\$21.34
83891, 83892, 83896, 83903, 83908, 83912	MTHFR Genotype	\$5.68, \$5.68, \$5.68, \$23.74, \$23.74, \$5.68	\$5.68, \$5.68, \$5.68, \$5.84, \$5.84, \$5.68
TOTAL REIMBURSEMENT		\$727.35	\$599.09

* = Only billed once per panel; other codes billed for each test.

90. However, HDL testing could be more expensive. For example, testing services

performed for E.S.Z., a Medicare patient living in South Carolina referred to HDL by Dr. Miller on January 4, 2011, consisted of the following:

CPT CODE	TEST	AMOUNT BILLED	MEDICARE PAYMENT
80061	Lipid Panel	\$46.00	\$0.00
82726	Long Chain Fatty Acids	\$58.00	\$25.41
82664	Electrophoretic Test	\$69.00	\$44.97
83695	Assay of Lipoprotein(a)	\$44.00	\$18.22
83698	Assay Lipoprotein pla2	\$110.00	\$0.00
83701	Lipoprotein bld hr fraction	\$67.00	\$34.93
83876	Assay myeloperoxidase	\$113.00	\$47.77
83891	Molecule isolate nucleic	\$13.00	\$5.51
83892	Molecular diagnostics	\$78.00	\$33.06
83896	Molecular diagnostics	\$130.00	\$55.10
83903	Molecule mutation scan	\$440.00	\$188.64
83908	Nucleic acid signal ampli	\$275.00	\$117.90
83912	Genetic examination	\$13.00	\$5.51
TOTAL		\$1456.00	\$577.02

91. Patient ESZ's records demonstrate that Medicare (and presumably other insurers and patients without insurance) could be billed more than \$1,400 for an HDL testing episode. Upon information and belief, the total reimbursement for ESZ's testing (approximately \$577) would have been the normal range for the tests HDL usually performs for Dr. Miller's patients.

92. During 2012, HDL began offering the EarlyCDT-Lung test, a blood test to aid in the early detection of lung cancer in high risk patients, including long-term smokers and ex-smokers, by focusing on tumor antigens involved in the development of lung cancer. The CPT Code for HDL's EarlyCDT-Lung test is 83520, and the Medicare reimbursement was \$18.34. Although offered by HDL, the EarlyCDT-Lung test was actually performed by OncImmune (USA) LLC.

93. HDL tests were paid for by a number of commercial insurance providers in California

and Illinois, including, but not limited to, Aetna, BCBS, Cinga, Humana, and UHC.

94. Under P&H agreements with referring physicians, HDL paid referral fees for patients covered by commercial insurance and government payors, including Medicare, TRICARE, and Medicaid.

B. Singulex, Inc. (“Singulex”)

95. Singulex, Inc. is a Delaware for-profit corporation. Singulex’s laboratory is headquartered at 1650 Harbor Bay Parkway, Suite 200, Alameda, California 94502. Singulex is privately held.

96. Singulex claims to be a “Leader in Advanced Cardiovascular Monitoring,” by providing “high-value, advanced tests for the diagnosis and monitoring of chronic diseases.” Singulex claims that its testing services improve patient care and reduce healthcare costs, and also “empower physicians and patients to better manage heart health” by “providing physicians with information that can allow them to earlier diagnose, better monitor, and more effectively manage chronic disease progression prior to the onset of acute clinical symptoms.”

97. Singulex laboratory testing that is relevant to this *Qui Tam* Complaint includes Singulex’s Advanced Cardiovascular disease (CVD) Testing Menu, which includes tests for Cardiopathology/Heart Function and Vascular Inflammation.

98. At all relevant times, Singulex did business in 28 states. Singulex’s NPI is 1184859191.

99. At all relevant times, Singulex Advanced Panel, which allegedly determines a patient’s cardiac risk, included, but was not limited to, the following tests:

CPT CODE	TEST	SOUTH CAROLINA MEDICARE REIMBURSEMENT RATE	NORTH CAROLINA MEDICARE REIMBURSEMENT RATE

84484	Cardiac Troponin-I	\$13.94	\$13.94
83520	Interleukin-6	\$18.34	\$18.34
83520	Interleukin-17A	-	-
TOTAL		\$32.28	\$32.28

100. Many of the Singulex requisition forms showed that Dr. Miller referred most of his patients to Singulex for the Singulex Advanced Panel.

101. Singulex tests were also paid for by a number of commercial insurance providers in California and Illinois, including, but not limited to, Aetna, BCBS, Cigna, and Humana.

102. Under P&H agreements with referring physicians, HDL and Singulex paid referral fees for patients covered by commercial insurance and Government payors, including Medicare, TRICARE, and Medicaid.

103. Neither HDL nor Singulex employed laboratory technicians to draw blood from patients referred to them by physicians. Instead, HDL and Singulex blood samples were drawn, processed, and shipped to HDL and Singulex laboratories by independent laboratories such as LabCorp, or by physicians who employed their own phlebotomist or lab technician.

VI. BACKGROUND ON FEDERAL AND STATE HEALTH CARE PROGRAMS

A. The Medicare Program

1. Medicare Payments: Only Medically Necessary Services

104. In 1965, Congress enacted Title XVIII of the Social Security Act, which established the Medicare Program to provide health insurance for the elderly and disabled. Medicare is a health insurance program for: people age 65 or older; people under age 65 with certain disabilities; and people of all ages with end-stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).

105. Payments from the Medicare Program come from a trust fund – known as the Medicare Trust Fund – which is funded through payroll deductions taken from the national work force, in addition to government contributions. Over the last fifty-three years, the Medicare Program has enabled the elderly and disabled to obtain necessary medical services from medical providers throughout the United States.

106. The Medicare Program is administered through the U.S. Department of Health and Human Services (“HHS”) and, specifically, the Centers for Medicare and Medicaid Services (“CMS”), an agency of HHS. Much of the daily administration and operation of the Medicare Program is managed through private insurers under contract with the federal Government (particularly CMS).

107. Medicare now has four parts: Part A (Hospital Insurance); Part B (Medical Insurance); Part C (Managed Care Plans); and the recently enacted Part D (Prescription Drug) Program.

108. Many of the patients impacted by the fraud described herein were also beneficiaries of Part C Plans.

109. Part A helps cover inpatient care in hospitals, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). Part A also helps cover hospice care and some home health care.

110. Part B helps cover doctors’ services and outpatient care, including emergency care. Part B helps pay for covered health services and supplies when they are medically necessary. Over the last forty years, the Medicare Program has enabled the elderly and disabled to obtain necessary medical services from medical providers throughout the United States.

111. Under Part B, the federal government contracts with insurance companies and other

organizations known as “carriers” or “Medicare Administrative Contractors” (“MACs”) to handle payment for physicians’ services in specific geographic areas. These private insurance companies, or “Medicare Carriers,” are charged with and responsible for accepting Medicare claims, determining coverage, and making payments from the Medicare Trust Fund. Laboratory testing provided on an out-patient basis is typically covered through Part B.

112. Part D provides beneficiaries with assistance in paying for out-patient prescription drugs. Under Part D, Medicare beneficiaries must affirmatively enroll in one of many hundreds of Part D plans (“Part D Sponsors”) offered by private companies that contract with the federal government. Part D Sponsors are charged with and responsible for accepting Part D prescription claims, determining coverage, and making payments from the Part D funds.

113. The principal function of Medicare intermediaries and carriers is to pay the claims of Medicare providers, and to audit such claims to ensure that providers follow the strictures of the Medicare Program. The Medicare carriers who receive laboratory testing claims at issue here are: for HDL in Virginia, Palmetto GBA (11302, MAC-Part B); for Singulex in Northern California, Palmetto GBA (01102, MAC-Part B); and for LabCorp in North Carolina, Palmetto GBA (11502, MAC-Part B).

2. Medicare Only Pays for Medically Necessary Clinical Laboratory Testing

114. Part B pays for clinical laboratory testing performed by companies such as LabCorp, HDL, and Singulex. These independent laboratories perform testing on specimens (also known as “samples”) from patients referred to the “independent” laboratory by his or her physician.

115. As a condition of payment by Medicare, diagnostic laboratory tests must be ordered by a physician who is treating the beneficiary, that is, the physician who furnishes a consultation

or treats a beneficiary for a specific medical problem. The physician must also use the results in the management of the beneficiary's specific medical problem. 42 C.F.R. § 410.32(a).

116. Medicare does not cover purely prophylactic lipid testing (lipid screening):

Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, etc.

Once a diagnosis is established, one or several specific tests are usually adequate for monitoring the course of the disease. Less specific diagnoses (for example, other chest pain) alone do not support medical necessity of these tests.

The Medicare National Coverage Determination on Lipid Testing National Coverage Determination (NCD) for Lipid Testing (190.23), *available at* <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=102&ncdver=2&bc=AAEAAAAAAAAAAA&>.

117. But when a patient is placed on dietary therapy or prescribed medication for high cholesterol, Medicare pays for periodic lipid testing. Medicare will cover “[a]ny one component of the panel or a measured LDL may be medically necessary up to six times the first year for monitoring dietary or pharmacologic therapy... If no dietary or pharmacological therapy is advised, monitoring is not necessary.” National Coverage Determination (NCD) for Lipid Testing (190.23). Medicare also pays for lipid testing once annually for patients on “long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels.” *Id.*

118. The physician who orders clinical laboratory services “must maintain documentation of medical necessity in the beneficiary’s medical record.” 42 C.F.R. § 410.32(d)(2).

119. Section 1862(a)(1)(A) of the Social Security Act provides that Medicare payment may not be made for services that are not reasonable and necessary. To participate in Medicare, providers must assure that their services are provided economically and only when, and to the extent, they are medically necessary. Medicare will only reimburse costs for medical services that are needed for the prevention, diagnosis, or treatment of a specific illness or injury.

120. As a condition for Medicare payment, a physician must certify the necessity of the services and, in some instances, recertify the continued need for those services. *See* Sections 1814(a)(2) and 1835(a)(2) of the Social Security Act; *see also* 42 C.F.R. § 424.10. In order for the federal Government to cover Part A or Part B services, or a Part C plan to provide coverage, all care must be “medically necessary.”

121. Medical care is “medically necessary” when it is ordered or prescribed by a licensed physician or other authorized medical provider, and Medicare determines that the care is necessary and proper (or a Part C insurer agrees that the plan covers such care). Services or supplies that are needed for the diagnosis or treatment of a medical condition must meet the standards of good medical practice in the local area.

3. The Independent Laboratory Bills Medicare for Testing Services

122. The majority of laboratory testing services are paid by Medicare on a fee-for-service basis. Medicare pays for most outpatient clinical laboratory services based on the Clinical Laboratory Fee Schedule in accordance with Section 1833(h) of the Social Security Act. The Medicare payment to the laboratory is the lesser of the laboratory’s actual charge, the local fee for a geographic area, or a national limit. In accordance with the Social Security Act, national limits are set at a percentage of the median of all local fee schedule amounts for each laboratory test code. Each year, fees are updated for inflation based on the percentage change in the Consumer Price Index. However, legislation by Congress can modify the update to the fees. Thus, under the

Clinical Laboratory Fee Schedule, the amount paid to the lab is usually the National Limitation Amount (“NLA”). Medicare Claims Processing Manual [Pub. 100-4] Chapter 16, Section 20. The Clinical Laboratory Fee Schedule is updated annually.

123. The clinical laboratory that provides the testing services bills the Government health programs directly, including Medicare. Medicare Part B pays approximately 80 percent of the Medicare-approved amount for these testing services.

124. The laboratory bills Medicare from the location the test is performed. For example, claims for tests performed at Defendant LabCorp’s facility in North Carolina are submitted from its consolidated billing center in North Carolina.

125. A clinical laboratory must accept assignment of the Medicare beneficiary’s benefit in order to receive Part B payment for laboratory tests based on the Laboratory Fee Schedule. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 30.1 - Mandatory Assignment for Laboratory Tests. Thus, Part B deductibles and coinsurance (co-payments) do not apply to laboratory services provided by a physician or by an independent laboratory. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 30.3 - Method of Payment for Clinical Laboratory Tests - Place of Service Variation.

126. The clinical laboratory submitting the claim to a federal healthcare program must maintain documentation it receives from the ordering physician, as well as documentation that the information that the lab submitted with the claim accurately reflects the information it received from the ordering physician or non-physician practitioner. 42 C.F.R. § 410.32(d)(2)(ii).

127. During claims review, CMS may deny claims by laboratories where documentation provided does not demonstrate that the service is reasonable and necessary, or where the providers fail to provide documentation requested to establish medical necessity. *Id.* § 410.32(d)(3)(ii).

128. The entity submitting the claim may request from the referring physician additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s). *Id.* § 410.32(d)(3)(iii).

129. If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, the medical necessity criteria in Chapter 15 of the Medicare Benefit Policy Manual, an educational contact with the prescribing physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the carrier is assured that the physician prescribes such services only when the criteria are met. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.2.

130. Medicare Managed Care (Part C) plans are provided by private insurance companies who administer federal healthcare benefits for eligible beneficiaries. Medicare Advantage Plans must cover all of the services that original Medicare (Parts A and B) covers. However, if a beneficiary is in a Medicare Advantage Plan, some benefits are still covered under original Medicare (such as hospice care and some costs for clinical research studies). All Medicare Advantage Plans cover emergency and urgently needed care. Medicare Advantage plans can choose not to cover the costs of services that aren't medically necessary under Medicare.

131. Like traditional Medicare, claims submitted to Medicare Part C plans that are tainted by inducements in violation of the federal AKS constitute violations of the federal FCA. These claims also violate the insurance fraud statutes in California and Illinois.

4. Limits on Medicare Payments for Blood Draws (Venipuncture)

132. In addition to payment for the laboratory testing service itself, CMS may (and usually does) make a separate payment to providers for collection of the specimen. Medicare reimburses medical providers a specimen collection fee for drawing a blood sample through

venipuncture (*i.e.*, inserting into a vein a needle with syringe or vacutainer to draw the specimen) or collecting a urine sample by catheterization. *Id.*, Section 60.1.

a. Medicare Pays for Blood Draws (Venipuncture) by a Physician

133. Medicare reimburses a physician for a blood specimen collection (venipuncture) only when (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen, and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen. *Id.*, Section 60.1.1 - Physician Specimen Drawing, (Rev. 1, 10-01-03).

134. A physician who performs the blood draws on his or her own patients for blood samples that are then sent to independent laboratories reports the service with HCPCS Code 36415, “collection of venous blood by venipuncture.” According to the 2012 Clinical Diagnostic Laboratory Fee Schedule for Medicare, the fee for HCPCS Code 36415 (venipuncture) was \$3.00.

b. Medicare Pays for Blood Draws (Venipuncture) by a Clinical Laboratory

135. Medicare allows separate charges by laboratories for drawing blood, whether or not the blood is referred to a hospital or independent laboratory. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.2 - Independent Laboratory Specimen Drawing (Rev. 1, 10-01-03). In 2012, the service code and payment for specimen collection by a laboratory was also HCPCS 36415.

136. Medicare does not pay the collection (“blood draw”) fee to anyone who has not actually extracted the specimen. In addition, only one collection fee is allowed for each type of specimen per patient encounter, regardless of the number of specimens (*i.e.*, vials of blood) drawn. *Id.*, Section 60.1.

137. Medicare does not pay for routine handling of blood samples referred by one

laboratory to another. *See Id.*, Section 60.1.2 – Independent Laboratory Specimen Drawing (Rev. 1, 10-01-03).

138. Any payment for blood draws or processing that is in excess of the Medicare reimbursement for venipuncture, \$3, is considered to be in excess of fair market value, otherwise referred to as an “above-market” payment.

139. Since at least 1994, HHS-OIG has made clear that “[w]hen a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business.” *OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services* (issued October 1994), available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>.

B. The Medicaid Program

140. Medicaid is the state-federal funded program for low income children and families, the elderly and people with severe disabilities. Congress created Medicaid in 1965, at the same time as Medicare, when Title XIX was added to the Social Security Act.

141. Medicaid is the largest source of funding for medical and health-related services for America’s poorest people.

142. Medicaid is a cooperative federal-state public assistance program which is administered by the states. CMS is the federal agency that administers the Medicaid program, and requires all states to provide certain mandatory services. However, because states must also provide funding for their Medicaid program, each state chooses several optional services they wish to provide in addition to the mandatory Medicaid services.

143. Funding for Medicaid is shared between the federal Government and those state Governments that choose to participate in the program. Federal support for Medicaid is substantial, often exceeding 50% of state Medicaid program funding. In 2012, for example, the federal

Government provided 70.43% of the funding for Medicaid programs in South Carolina. The remaining funds were provided by the relevant state Governments.

144. Title XIX of the Social Security Act allows considerable flexibility within the States' Medicaid plans and, therefore, specific Medicaid coverage and eligibility guidelines vary by state.

1. Medicaid Programs Pay for Necessary Clinical Laboratory Testing

145. Like the Medicare Program, Medicaid only covers health services or supplies, including laboratory testing, that are medically necessary for the diagnosis or treatment of a medical condition, in keeping with the standards of good medical practice in the local area. While Medicaid reimbursement for laboratory testing varies by state, there is generally a requirement that the testing is medically necessary.

146. For example, South Carolina Medicaid covers laboratory testing only if it is “medically necessary for the appropriate care of the patient.” South Carolina Health and Human Services Physicians Provider Manual, Section 2, p. 190.

2. Medicaid Coverage for Blood Draws (Venipuncture)

147. Like Medicare, state Medicaid programs also permit a physician to bill for venipuncture when the physician's office actually draws blood samples to be sent to independent clinical laboratories for testing.

148. For example, South Carolina Medicaid allows for physicians who perform blood draws to charge Medicaid using Code 36415. The physician or clinic provider may charge the draw fee regardless whether he performs the testing. However, a physician may not bill for a blood draw alone and also bill for an office visit or lab test on the same date. *Id.*, Section 2, p. 191.

C. Other Government-Funded Health Care Programs Pay for Laboratory Tests

1. TRICARE/CHAMPUS and Other Federal Healthcare Benefits

149. In addition to Medicaid and Medicare, the federal Government reimburses a portion of the cost of laboratory testing services under several other federal health care programs, including, but not limited to, CHAMPUS/TRICARE, CHAMPVA and the Federal Employees Health Benefit Program (“FEHBP”).

150. CHAMPUS/TRICARE, administered by the U.S. Department of Defense (“DOD”), is a health care program for individuals and dependents affiliated with the armed forces. It offers military families a choice of three options: TRICARE Prime, TRICARE Extra, and TRICARE Standard (formerly known as CHAMPUS (Civilian Health & Medical Program for Uniformed Services), a health care plan for military dependents and retirees operated by the DOD.

151. CHAMPVA, administered by the U.S. Department of Veteran Affairs, is a health care program for the families of veterans with a 100% service-connected disability.

152. The FEHBP, administered by the U.S. Office of Personnel Management, provides health insurance for hundreds of thousands of federal employees, retirees, and survivors.

153. Like Medicare, TRICARE and other federal healthcare benefit programs cover only medically necessary inpatient and outpatient care. TRICARE defines medically necessary care as services or supplies provided by a hospital, physician, and/or other provider for the prevention, diagnosis, and treatment of an illness, when those services or supplies are determined to be consistent with the condition, illness, or injury; provided in accordance with approved and generally accepted medical or surgical practice; not primarily for the convenience of the patient, the physician, or other providers; and not exceeding (duration or intensity) the level of care, which is needed to provide safe, adequate and appropriate diagnosis and treatments. *See* http://www.usfhp.net/pdfs/Member_Handbook.pdf.

154. TRICARE always requires a referral and/or prescription from the member’s

primary care physician for treatment, including laboratory tests.

2. Private Insurance Pays for Medically Necessary Laboratory Tests

155. Private insurance plans also pay for laboratory testing provided by LabCorp, HDL, and Singulex. Upon information and belief, the contracts for those private insurers whose patients are drawn into the LabCorp, HDL, and Singulex referral scheme mirror the Medicare and Medicaid requirements by mandating that laboratory testing billed to private insurers is not the result of an illegal inducement, and is medically necessary.

156. In particular, as alleged below, the CIFPA and ILCFPA both prohibit the submission of claims to insurers for services where the insured patients were procured through improper inducements.

VII. THE APPLICABLE LAW

A. The Federal False Claims Act (“FCA”) – Overview

157. Section 3729 of the Federal FCA provides as follows:

“(a) Liability for Certain Acts -

(1) IN GENERAL - Subject to paragraph (2), any person who -

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false

record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

B. The Federal Anti-Kickback Statute (“AKS”)

158. Enacted in 1972, the federal AKS, 42 U.S.C. § 13207b(b), protects patients and federal healthcare programs from fraud and abuse by curtailing the corrupting influence of money on healthcare decisions. When a company pays kickbacks to a doctor in order to induce him/her to use the company’s products or services, it fundamentally compromises the integrity of the doctor-patient relationship. Government-funded healthcare programs, such as Medicare and Medicaid, rely upon physicians to decide what treatment is appropriate and medically necessary for patients, and, therefore, payable by such healthcare program.

159. The federal AKS makes it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce a person: (1) to refer an individual to a person for the furnishing of any item or service covered under a federal health care program; or (2) to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a federal health care program. 42 U.S.C. § 1320a-7b(b)(1) and (2).

160. A violation of the AKS constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Any party convicted under the AKS must be excluded (*i.e.*, not allowed to bill for any services rendered) from Federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1).

161. The AKS not only prohibits outright bribes to a physician, but also prohibits offering or paying for any remuneration to a physician that has, as one purpose, inducement of the

physician's referrals to federal health care programs. Claims that include items or services resulting from a violation of the AKS are false or fraudulent under the FCA. 42 U.S.C. §1320a-7b(g).

162. The term "remuneration" encompasses anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. 42 U.S.C. § 1320a-7b(b)(1).

163. The AKS has been interpreted by the majority of federal courts to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 460, 468 (D.S.C. 2016), *appeal dismissed sub nom. United States ex rel. Lutz v. United States*, 853 F.3d 131 (4th Cir. 2017) ("Moreover, in FCA cases involving AKS violations, courts have found scienter where one purpose of the remuneration was to induce referrals." (citations omitted)); *see also United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985) (holding that the Anti-kickback statute is violated if "one purpose of the payment was to induce future referrals ... even if the payments were also intended to compensate for professional services."); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (adopting the holding in *Greber*); *Feldstein v. Nash Community Health Services*, 51 F. Supp. 2d 673 (E.D.N.C. 1999) (recognizing that the Medicare fraud statute is violated if "one purpose of the payment was to induce future referrals," and citing *Kats* and *Greber*).

164. Proof of an explicit *quid pro quo* is not required to show a violation of an anti-bribery statute such as the AKS. "It is well settled that while bribery must involve a *quid pro quo*, there is no need to prove an expressed agreement by the parties." *Walker v. Rivera*, 820 F. Supp. 2d 709, 718 (D.S.C. 2011) (Gergel, J.), *aff'd*, 468 F. App'x 341 (4th Cir. 2012) (citing *United States v. Quinn*, 359 F.3d 666, 673 (4th Cir. 2004)).

165. HHS has published “safe harbor” regulations that define practices not subject to the AKS because such practices are unlikely to result in fraud or abuse. 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is only afforded to those arrangements that precisely meet all of the conditions set forth in the safe harbor. As further explained herein, none of the practices at issue in this *Qui Tam* Complaint meet these safe harbor regulations.

166. Compliance with the AKS is an express condition of payment under Government healthcare programs, including the Medicare and Medicaid programs, and that condition applies regardless of whether the kickback payor or recipient is submitting the claim to the Government. Claims that arise from a kickback scheme are *per se* false, and violate the False Claims Act, because they are the result of a kickback – no further express or implied false statement is required to render such infected or tainted claims false, and none can wash the claim clean.

167. On March 23, 2010, as part of the Patient Protection and Affordable Care Act, PL 111-148 (“PPACA”), the AKS was amended to explicitly provide that a claim resulting from a violation of the AKS is a violation of the False Claims Act. Specifically, the AKS was amended by adding subsection (g) to 42 U.S.C. § 1320a-7b. Under that subsection “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code.”

168. In addition, Section 6402(a) of the PPACA established section 1128J(d) in the Social Security Act regarding reporting and returning Medicare and Medicaid overpayments. Section 1128J(a) requires a person who has received an overpayment to report and return the overpayment by the later of (i) 60 days after the overpayment was identified, or (ii) the date any

corresponding cost report is due. The knowing and improper failure to return an overpayment subjects the recipient to liability under the federal False Claims Act, 31 U.S.C. § 3730(a)(1)(G).

C. Claims for Lab Tests Tainted by AKS Violations Are Fraudulent

1. HHS-OIG: Fraud Alert on Lab Services and Tainted Referrals

169. Since at least 1994, the OIG has issued fraud alerts on clinical laboratory services. OIG has noted that “[m]any physicians and other health care providers rely on the services of outside clinical laboratories to which they may refer high volumes of patient specimens every day. The quality, timeliness and cost of these services are of obvious concern to Medicare and Medicaid patients and to the programs that finance their health care services. Because the physician, not the patient, generally selects the clinical laboratory, it is essential that the physician’s decision regarding where to refer specimens is based only on the best interests of the patient.” *Id.*

170. OIG has stated that “[w]henver a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business.” *Id.*

171. Likewise, “whenever a referral source solicits or receives anything of value from the laboratory,” the same inference (that the thing of value is offered to induce the referral of business) may be made. By “fair market value” OIG means “value for general commercial purposes,” which “must reflect an arm’s length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them.” *Id.*

172. OIG has issued a Special Fraud Alert regarding kickbacks associated with a lab that provides phlebotomy services to referring physicians. In particular, OIG has noted:

- When permitted by State law, a laboratory may make available to a physician’s office a phlebotomist who collects specimens from patients for testing by the

outside laboratory.

- While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the AKS, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff.
- In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the AKS.

Id.

173. On June 25, 2014, the OIG issued a Special Fraud Alert which provided:

- The OIG had “repeatedly emphasized that providing free or below-market goods or services to a physician who is a source of referrals, or paying such a physician more than fair market value for his or her services, could constitute illegal remuneration under the anti-kickback statute.”
- The “Special Fraud Alert supplements these prior guidance documents and advisory opinions and describes two specific trends OIG has identified involving transfers of value from laboratories to physicians that we believe present a substantial risk of fraud and abuse under the anti-kickback statute.”
- Earlier fraud alerts made clear that: 1) “[w]henver a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business;” and 2) “when a laboratory pays a physician more than fair market value for the physician's services or for services the laboratory does not actually need or for which the physician is otherwise compensated, the anti-kickback statute is

implicated. Such payments are suspect under the anti-kickback statute because of the implication that one purpose of the payments is to induce the physician's Federal health care program referrals. OIG also historically has been concerned with arrangements in which the amounts paid to a referral source take into account the volume or value of business generated by the referral source."

- The Special Fraud Alert was issued in response to OIG becoming aware of arrangements under which clinical laboratories, either directly or indirectly (such as through an arrangement with a marketing or other agent) providing remuneration to physicians to collect, process, and package patients' specimen. ("Specimen Processing Arrangements").
- OIG identified the characteristics of a Specimen Processing Arrangement that evidence an unlawful purpose, that is an inducement in violation of the AKS, including: payment exceeding fair market value; payment for services also made by a third party, including Medicare; payments made directly to the ordering physician rather than to the physician's group practice; payments are made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals; payment is conditioned on the ordering of either a specific volume or type of tests or test panel, especially if the panel includes duplicative tests (*e.g.*, two or more tests performed using different methodologies that are intended to provide the same clinical information), or tests that otherwise are not reasonable and necessary or reimbursable.
- OIG also stated that where specimen processing payments are made to the

physician or the physician's group practice but the specimen processing is actually being performed by a phlebotomist placed in the physician's office by the laboratory or a third party, this is also evidence that the payments are made for an unlawful purpose.

- OIG further noted that "because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible "kickback" arrangement, physicians who enter into Specimen Processing Arrangements with laboratories also may be at risk under the statute."

174. As described below, under sham compensation arrangements between HDL and Singulex, referring physicians received above-market "processing" fees from HDL and Singulex.

175. The AKS is implicated by LabCorp's conduct because: 1) the LabCorp technician performed the blood specimen draws and processing tasks related to the HDL and Singulex referrals. Under the sham specimen processing arrangements between the physicians and HDL and Singulex, these tasks were the responsibility of the physician or physician's group, and 2) LabCorp's conduct facilitated the delivery of the patient referrals (blood specimens) to HDL and Singulex in exchange for above-market P&H fees.

D. Violations of California and Illinois Insurance Fraud Statutes

176. Both California and Illinois have *qui tam* statutes that permit relators to raise allegations of fraud by individuals or entities against private insurance companies. The statutes operate similarly to the FCA and are written to prevent fraud occurring in the massive private healthcare insurance market.

177. Defendant LabCorp is paid routinely by private insurers that cover California-based and Illinois-based patients who have been referred for testing as a result of the LabCorp scheme.

178. Upon information and belief, private healthcare insurance companies in California

and Illinois require the same conditions of payment and prohibitions on unnecessary medical testing found in the Medicare and Medicaid programs.

179. The CIFPA prohibits the following:

It is unlawful to knowingly employ runners, cappers, steerers, or other persons...to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer.

Cal. Ins. Code § 1871.7(a). Any person or entity found in violation of this section or specifically identified corollary criminal code sections is subject to civil penalties ranging from \$5,000.00 to \$10,000.00 per false claim plus three times the amount of each false claim for compensation from an insurer. *Id.*, § 1871.7(b).

180. Under the CIFPA, any interested person may bring a sealed civil action for a violation of Section 187.7 on behalf of the State of California. *Id.* § 1871.7(e)(1), (2). If the relator is ultimately successful and the District Attorney or the Insurance Commissioner intervenes in the lawsuit, the relator is entitled to the recovery of fees, expenses, and a relator's share of between 30% and 40% according to the priority specified in the statute. *Id.* § 1871.7(g)(1)(A)(iii)(I), (IV). If neither the District Attorney nor the Insurance Commissioner intervene and the relator is successful in settling his/her lawsuit or attaining final judgment, the relator may receive between 40% and 50% of the proceeds plus costs and expenses. *Id.* § 1871.7(g)(2)(A).

181. The Illinois Insurance Claims Fraud Prevention Act ("ILCFPA") is similar to the CIFPA. In Section 92/5(a), the ILCFPA prohibits kickbacks and states:

...[I]t is unlawful to knowingly offer or pay any remuneration directly or indirectly, in case or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer.

If a defendant is in violation of Section 92/5(a) or specifically identified corollary criminal code

sections, he/she must reimburse three times the amount of money defrauded as well as civil penalties ranging from \$5,000.00 to \$10,000.00 per fraudulent claim. 740 Ill. Comp. Stat. § 92/5(b).

182. Pursuant to Section 15 of the ILCFPA, an interested person may bring a sealed civil action for a violation of the ILCFPA on behalf of him/herself and the State of Illinois. *Id.* § 92/15(a), (b). If the State’s Attorney and/or the Attorney General intervene in the *qui tam* action, and it is ultimately successful, the relator is entitled to at least 30% of the recovery. *Id.* § 92/25(a). If neither government entity intervenes and the relator successfully pursues the lawsuit on his/her own, the relator is entitled to recover not less than 40% of the proceeds. *Id.* § 92/25(b).

183. Relators are the original sources of the allegations under the CIFPA and ILCFPA.

VIII. ALLEGATIONS: DEFENDANT LABCORP, AND CO-CONSPIRATORS HDL AND SINGULEX, PROVIDE ILLEGAL INDUCEMENTS FOR PATIENT REFERRALS FOR LABORATORY TESTS

A. Overview of HDL and Singulex Operations

184. Neither HDL nor Singulex employed its own outside sales force. Instead, Dent, Johnson, and BlueWave Healthcare Consultants, Inc. (“BlueWave”) served as the marketing agent for HDL and Singulex. BlueWave was formed in early 2010 by Dent and Johnson.

185. During the relevant time period, Dent, Johnson, and BlueWave sales representatives aggressively promoted Singulex and HDL products to physicians and physician practices throughout the country.

186. On or about June 1, 2010, BlueWave, through its principals, Dent and Johnson, signed an agreement with Singulex for the exclusive right to promote Singulex testing services to physicians in certain sales territories. The BlueWave sales territories for Singulex later expanded.

187. The BlueWave-Singulex marketing agreement mandates that Singulex pay physicians and independent lab companies for processing and handling of blood samples.

188. In early 2010, BlueWave also entered into an agreement with HDL for the near-exclusive right to promote HDL products to physicians across the United States, which was similar to the agreement between Singulex and BlueWave. Relators further allege upon information and belief, and therefore aver, that HDL was similarly required to pay physicians and independent lab companies for processing and handling fees for HDL tests.

B. Relators Discover HDL and Singulex Payments to Dr. Miller for Referrals

189. As stated above, Relator Webster has been a registered nurse for Dr. Miller's practice since May 2008. Relator Lutz was contracted in early 2011 to assist Dr. Miller with, among other things, billing. Relators have obtained knowledge and information that LabCorp, HDL, and Singulex participate in a scheme to fraudulently induce Dr. Miller and other physicians to refer thousands of patients for testing that is not reimbursable by Government healthcare programs.

1. Lloyd Miller, MD

190. During the relevant time period, Lloyd Miller Jr., MD was a primary-care physician licensed to practice in the state of South Carolina.

191. From September 2011, Dr. Miller did business as Internal Medicine of Carolinas (owned by Carolinas Medical Alliance), 2501 S. Vance Drive, Suite B, Florence, South Carolina 29505. Before that time, Dr. Miller did business as Internal Medicine Associates, PC, with an office located at 805 Pamlico Hwy, Suite B 310, Florence, South Carolina 29505. Internal Medicine Associates was also the alter ego of Dr. Miller.

192. LCM Enterprises of Florence, Inc. ("LCM"), was a South Carolina corporation formed in 1991 by Lloyd Miller, MD, whose principal place of business is located at 2501 South Vance Drive, Suite B, Florence, South Carolina 29505. LCM was also the alter ego of Lloyd Miller, MD.

193. Dr. Miller's staff has included, but was not limited to, the following employees: Ginger Tolson, Office Manager; Relator, Kayla Webster, RN, Nursing Supervisor; and office assistants, Mandy Floyd and Kandice Smith. Dr. Miller never employed a phlebotomist to draw blood for patients' laboratory tests.

C. BlueWave, HDL & Singulex Lure Physicians with Lucrative "Processing" Fees

1. BlueWave and HDL Redirect Dr. Miller's Referrals to HDL

194. Beginning in late 2009 or early 2010, Dent, Johnson, and other BlueWave marketing agents began promoting HDL testing services. Immediately, Dr. Miller stopped referring patients to Berkeley HeartLab ("Berkeley"), a clinical laboratory which provides testing related to coronary disease, and began referring his patients to HDL.

a. "Berkley" is Pre-Printed on His Encounter Page

195. Before they began marketing HDL clinical laboratory testing services, BlueWave's sales representatives (Tony Carnaggio and Dent) marketed Berkeley tests related to coronary disease to Dr. Miller. In fact, Dr. Miller referred patients to Berkeley so often that the Berkeley (misspelled "Berkley") test was added to Dr. Miller's pre-printed patient encounter sheet.

196. Dr. Miller ordered Berkeley tests for nearly every patient in his robust practice.

b. After Dr. Miller Abruptly Shifts to HDL, "Berkeley" Means "HDL"

197. Relator Webster observed Dr. Miller abruptly stop referring patients to Berkeley on or about January 1, 2010. Dr. Miller immediately began referring all, or nearly all, his patients to HDL.

198. Soon after shifting patient referrals to HDL, Dr. Miller started receiving monthly payments from HDL that were calculated at \$20 for per patient listed on a "draw log" which accompanied the check from HDL to Dr. Miller.

199. HDL maintained the “draw log,” which listed each patient referred to HDL. One purpose of the monthly payments by HDL to Dr. Miller was to induce him to refer patients to HDL.

200. While Dr. Miller almost immediately changed his referrals from Berkeley to HDL, he did not immediately change his pre-printed patient encounter form. After January 1, 2010, when a patient’s encounter form was marked “Berkley,” this meant that the patient was referred to HDL for testing.

201. In addition to paying the \$20.00 fee for every patient listed on the “draw log,” to facilitate the referrals for testing, HDL provided Dr. Miller with pre-printed laboratory requisition forms, all of the necessary collection, and shipping supplies (blood collection tubes, bags, ice packs, shipping boxes and pre-paid FedEx labels). Dr. Miller’s office ordered these supplies, as needed, by sending a request to HDL via facsimile.

202. Dr. Miller’s staff did not use the blood draw “kits” provided by HDL. When Dr. Miller’s staff received the HDL blood draw supplies, they provided these to the phlebotomist provided by Defendant LabCorp.

203. The LabCorp technician stored the HDL blood draw supplies, drew blood samples for HDL testing, and processed the samples for HDL.

2. HDL Pays Referring Physicians, Including Dr. Miller, Bogus “Processing” Fees

204. As stated above, in March of 2011, Relator Lutz began to provide billing services for Dr. Miller. After March 2011, but before September 2011, in approximately August 2011, someone left an unmarked envelope at Relator Lutz’s office. When Ms. Lutz opened the envelope, it contained copies of payment checks from HDL and Singulex to Dr. Miller or his companies for bogus “processing fees.” It also contained copies of “draw logs,” lists of patients referred by Dr.

Miller to HDL and Singulex in support of each payment.

205. HDL paid Dr. Miller \$20 for each patient referred to HDL for laboratory testing.

206. When Relator Lutz closely examined the documents related to HDL's payments to Dr. Miller, she noted the following:

- From January 2010 through the end of 2012, HDL paid Dr. Miller an estimated \$133,300 for referrals of approximately 6,665 patients, or between 150 and 185 patients per month.
- Based on a review of the list of patients for whom Dr. Miller received payments from HDL, estimated conservatively, 47% of the patients referred by Dr. Miller to HDL were beneficiaries of government healthcare programs.

207. HDL's practice of offering and paying a \$20 per patient inducement to referring physicians, including Dr. Miller, continued until at least mid-2014.

3. HDL "Processing" Arrangements with Physicians, Including Dr. Miller, Are Bogus

208. In literature provided to physician customers, HDL described the many steps it considered part of the processing services that are the responsibility of referring physicians (after the blood draw), including the following:

- Immediately invert 8-10 times after blood draw;
- Allow to clot for 30 minutes in an upright position;
- Centrifuge for 15 minutes at 3000 rpm;
- Place tube in the biohazard bag provided with absorbent material;
- Place in refrigerator until ready for shipment;
- Place specimen(s) inside biohazard bag with absorbent pad;
- Complete required information on the requisition form;

- Place test requisition in the outside pouch of the biohazard bag;
- Place a frozen cool-pack brick in the bottom of Styrofoam cooler;
- Place three to four paper towels (for insulation) over the brick;
- Insert the refrigerated specimen bags in the Styrofoam cooler;
- Place two paper towels over the refrigerated specimens; and
- Immediately replace the Styrofoam cooler lid before closing the box.

209. HDL paid referring physicians under arrangements purporting to compensate physicians for “processing” blood samples for HDL tests.

210. Relators allege upon information and belief that HDL entered into bogus service arrangements with referring physicians in an attempt to disguise HDL’s inducements for referrals as market-value compensation for bona fide professional services.

211. In contrast to HDL’s product literature, Relator Webster observed that HDL’s referring physician, Dr. Miller, did not provide any substantive blood sample processing services. Rather, the lab technician provided to Dr. Miller’s office by Defendant LabCorp, performed all (or nearly all) of the blood processing services for patients referred to HDL.

212. Dr. Miller’s staff performed only minimal processing tasks on HDL blood samples: completing required information on the requisition form; attaching labels to tubes containing blood samples; placing test requisition in the outside pouch of the biohazard bag; placing a frozen cool-pack brick in the bottom of Styrofoam cooler and adding the refrigerated specimen bags; replacing the cooler lid; and closing the box.

213. The LabCorp technician assigned to Dr. Miller’s office performed all of the HDL blood draws, as well as most of the HDL processing tasks: immediately invert 8-10 times after blood draw; allow to clot for 30 minutes in an upright position; centrifuge for 15 minutes at 3000

rpm; place tube in the biohazard bag provided with absorbent material; and place in refrigerator until ready for shipment.

214. Even if the blood processing services were performed by Dr. Miller or his staff, the \$20 payment by HDL exceeded fair market value, and the total compensation to Dr. Miller was directly related to the number (volume) of his patient referrals.

215. Nonetheless, and without regard to the fair market value of Dr. Miller's services, HDL paid Dr. Miller the \$20 to perform minimal services on blood that is drawn and largely processed by Defendant LabCorp.

4. Singulex's Inducements: \$10 Per Referral Are Bogus "Processing" Fees

216. BlueWave became the exclusive marketing agent for Singulex in June 2010. About that same time, BlueWave, through its marketing agents, began promoting Singulex testing services to physicians in their sales territory, including Dr. Miller.

217. As stated above, when BlueWave's sales representatives (Carnaggio and Dent) marketed Berkeley clinical laboratory tests related to coronary disease, Dr. Miller had the "Berkley" ("B") test added to his patient encounter sheet, but he did not immediately change his pre-printed patient encounter form. Thus after January 1, 2010, when a patient was referred to HDL, the encounter form box next to "Berkley" was selected.

218. When BlueWave started marketing Singulex testing with HDL, Dr. Miller began referring patients to both HDL and Singulex. For example, Dr. Miller would note on the patient encounter sheet that the patient should have "Berkley/Singulex," or "B/S" testing when he was referring patients to HDL and Singulex.

219. During June or July 2010, Dr. Miller began to refer all of his patients for testing by both Singulex and HDL. Soon thereafter, Dr. Miller began to receive payments from Singulex of

\$10 per patient referral, in addition to the payment of \$20 per patient referral that he received from HDL. Thus, for patients referred to both HDL and Singulex, Dr. Miller received \$30 each time the patient was tested. Like the HDL payments, one purpose of the payments by Singulex was to induce Dr. Miller to refer patients to Singulex for testing.

220. When Relator Lutz examined the documents related to Singulex's payments to Dr. Miller, she noted the following:

- From July 2010 through the end of 2012, Singulex paid Dr. Miller an estimated \$55,540 for referrals of approximately 5,554 patients, or between 150 and 185 patient referrals per month.
- Based on a review of the list of patients for whom Dr. Miller received payments from Singulex, conservatively, 47% of the patients referred to Singulex were beneficiaries of government healthcare programs.

221. Singulex's practice of offering and paying a \$10-per-patient inducement to referring physicians, including Dr. Miller, continued until at least mid-2014. The Singulex checks to Dr. Miller were signed by Singulex's corporate controller.

222. HDL and Singulex kickback checks were made payable to the physician, the physician's practice, or a related corporate entity. For example, HDL and Singulex had a compensation arrangement with Dr. Miller, under which HDL and Singulex made payments to various entities associated with Dr. Miller. Both HDL and Singulex made payments to Dr. Miller through checks made payable to "Internal Medicine Associates, P.C." Singulex also made payments to Dr. Miller through checks made payable to "LCM Enterprises of Florence, Inc."

223. The named parties to the Singulex P&H "Agreement for Singulex Clinical Lab Cardiovascular Testing" are Singulex and "LCM," Dr. Miller's alter ego. Singulex's former CEO,

Philippe Goix, signed the processing and handling agreement on behalf of Singulex.

5. Singulex “Processing Services” Agreements Are False Records

224. Singulex entered into a sham agreement with Dr. Miller entitled “Agreement for Singulex Clinical Lab Cardiovascular Testing.” In the agreement, Singulex states that the physician, Dr. Miller, is paid the \$10 fee to perform the following “processing services”:

- The phlebotomy draw;
- Allocation of specimens into multiple vials as defined in the Singulex Specimen Collection Instructions;
- Assignment of labels to the vials;
- Packing of specimens into the Singulex shipping kits provided to the practice;
- Labeling of the shipment package; and
- Scheduling of shipment pickup.

225. Singulex also had literature which describes the tasks it considers part of the processing services to be performed by physicians who refer patients to Singulex for laboratory testing:

- Invert 4-5 times;
- Centrifuge for 15 minutes at 3000 RPM;
- Refrigerate;
- Place tube into front pouch of Specimen Transport Bag;
- Fold and place copies of completed requisition form and demographic sheet into back pouch of Specimen Transport Bag;
- Pack shipment box in order shown, with Specimen Transport Bags sandwiched between refrigerant gel; and

- Affix Singulex FedEx Airbill.

226. Relator Webster observed that Dr. Miller did not perform or pay for (by having his staff perform) processing services for Singulex blood samples as described as physician responsibilities in the “Agreement for Singulex Clinical Lab Cardiovascular Testing.” From the spring of 2011, LabCorp provided all of the blood draw services, and virtually all of the processing services for tests on patients referred by Dr. Miller to Singulex.

227. Dr. Miller’s staff had minimal involvement in handling Singulex blood samples: assignment of labels to the vials; packing of specimens into the Singulex shipping kits provided to the practice; folding and placing copies of completed requisition form and demographic sheet into back pouch of Specimen Transport Bag; and placing the blood samples in Singulex’s shipment box. It was not necessary for Dr. Miller to label the shipment package because Singulex provided prepaid, labeled FedEx boxes. In addition, the Singulex packages were picked up daily, so there was no need to schedule the pickups.

228. The LabCorp representative performed most of the blood processing tasks listed as Dr. Miller’s responsibilities in the “Agreement for Singulex Clinical Lab Cardiovascular Testing” and described in Singulex’s processing instructions for referring physicians: the phlebotomy draw; allocation of specimens into multiple vials per Singulex Specimen Collection Instructions; inverting 4-5 times; centrifuge for 15 minutes at 3000 RPM; placing the tube into front pouch of Specimen Transport Bag; and refrigerating the specimens.

229. In contrast to the Singulex processing agreement and product literature, Dr. Miller received Singulex’s \$10 fee per patient referral, but neither he nor his staff performed substantive blood processing services. Rather, the LabCorp technician in Dr. Miller’s office performed the majority nearly all of the processing services on blood samples referred to Singulex.

6. CMS Pays for Blood Draws, But Not “Processing” Services

230. Government healthcare programs, such as Medicare and Medicaid, reimburse physicians or laboratories only if their staff actually performs the blood draw (venipuncture). Thus, if Dr. Miller actually performed the blood draw, his fee would have been \$3.00. Because Dr. Miller did not perform the phlebotomy draw for HDL and Singulex tests, he was not entitled to a fee for blood collection.

231. Likewise, an independent laboratory, such as LabCorp, may bill for the venipuncture (blood draws) performed for Dr. Miller’s patients. Even then, the Medicare reimbursement for LabCorp would be \$3.00, which is significantly less than the \$20.00 HDL pays physicians for minimum “processing” services.

232. Where Defendant LabCorp performed the blood draw, it could only bill Government healthcare programs, including Medicare, for the venipuncture (blood draws). LabCorp would have received only one fee of \$3.00 per draw, even though it drew samples for LabCorp, HDL, and Singulex from a given patient.

233. Government healthcare programs such as Medicare do not reimburse physicians or laboratories for “processing” services for blood samples sent to laboratories. Where one laboratory (LabCorp) drew blood for another laboratory (HDL or Singulex), routine processing charges were not reimbursable services under Government healthcare programs. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.2.

234. Defendant LabCorp provided both blood draws and blood processing services for Dr. Miller’s patients referred to HDL for testing.

235. Instead, LabCorp performed the majority of processing services for HDL samples, but HDL paid the \$20 per patient “processing” fee directly to the referring physician, Dr. Miller.

236. Upon information and belief, there was an arrangement between HDL and LabCorp

regarding the draw fees for patients referred to HDL. Relators have reviewed LabCorp reports for Dr. Miller's patients who were beneficiaries of Government healthcare programs, including Medicare and TRICARE. They contain the computer printed notation: "Draw Fee to HDL." Neither Dr. Miller nor HDL was entitled to reimbursement for the blood draw or processing under Government programs or by private health insurance because LabCorp, not HDL, performed the blood draw.

237. Singulex paid draw fees to referring physicians who do not perform the venipuncture. The Singulex agreement states that Dr. Miller's staff was supposed to perform both the blood draw and the blood processing services in exchange for the \$10 processing fee. Defendant LabCorp, not Dr. Miller, performs the blood draw services. Thus, Dr. Miller was not entitled to the portion of the Singulex fee for the blood collection.

238. Similarly, Government healthcare programs reimburse physicians only if their staff actually performs the blood draw (venipuncture). Even then, the Medicare reimbursement is \$3, which is less than one third of the \$10 payment by Singulex to Dr. Miller.

239. Even if Dr. Miller's staff did perform the blood processing services for patients referred to Singulex, the \$10 payment by Singulex far exceeded fair market value for these services. The Singulex payments were also directly related to patient referrals.

240. Medicare does not pay for routine handling charges where a specimen is referred by one laboratory to another. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.2 - Independent Laboratory Specimen Drawing, (Rev. 1, 10-01-03).

241. Government healthcare programs do not reimburse for services such as refrigeration, processing, and shipping, which have only minimal value. A LabCorp representative demanded that Dr. Miller pay a \$5.00 fee per patient to draw blood and process blood samples for

both HDL and Singulex tests. Thus, the fair market value of the processing services related to Singulex tests alone was, at best, \$2.50.

242. Singulex's practice of offering and paying Dr. Miller an inducement of \$10.00 per patient referral continued until at least mid-2014.

7. HDL and Singulex's Arrangements with Dr. Miller Violate AKS

243. HDL and Singulex failed to meet any of the Safe Harbors to the AKS.

244. HDL and Singulex did not meet the requirements of the personal services exception to the AKS, 42 CFR § 1001.952 (d), which requires that HDL and Singulex meet all seven of the following elements:

- (1) The agency agreement is set out in writing and signed by the parties;
- (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent;
- (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a fulltime basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
- (4) The term of the agreement is for not less than one year;
- (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs;

- (6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and
- (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

245. The arrangements between HDL, Singulex, and Dr. Miller fail at least two of the requirements of 42 C.F.R. § 1001.952(d)(5). Payments by HDL and Singulex far exceed fair market value. In addition, payments by HDL and Singulex are “determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.”

246. HDL and Singulex kept careful records of both the patients referred and the inducements paid to each physician, including Dr. Miller. Under the guise of “processing fees” paid in exchange for the referrals, HDL and Singulex violated the federal AKS by paying physicians, including Dr. Miller, for patient referrals.

D. Defendant LabCorp Provides Physicians with Free Lab Services for Referrals

247. For most of Relator Webster’s employment, Dr. Miller’s staff did not perform either the blood draws or processing services for specimens drawn in Dr. Miller’s office when patients were referred for clinical laboratory testing.

248. On the very rare occasion when Dr. Miller’s staff would perform blood draws and processing services for his patients, Dr. Miller’s practice would bill Government healthcare programs only for the venipuncture using HCPCS Code 36415. The 2012 Medicare reimbursement

for the professional fee for a blood draw was \$3.00 per patient, irrespective of the number of samples (vials) drawn. Dr. Miller was not entitled to seek reimbursement for processing services from Medicare.

249. The vast majority of the time, Dr. Miller used a variety of independent laboratories to perform blood draws and processing services in his office for patients he referred for clinical laboratory testing.

250. From approximately late 2008 until September 2010, Dr. Miller's blood draws and processing services were performed by Executor Diagnostics, LLC. For the last couple of months of 2010 until January 2011, Spectrum Laboratory Network did blood draws and processing for Dr. Miller's patients. In early 2011, Solstas Lab Partners briefly performed lab technician services.

251. Relators believe that Defendant LabCorp began providing free lab services (blood draws and processing services) in Dr. Miller's office in spring 2011. Each day the LabCorp technician drew and processed HDL and Singulex specimens, she also drew and processed tests referred by Dr. Miller to LabCorp.

252. The LabCorp technician in Dr. Miller's office wore a LabCorp-provided lab coat and identifying name badge. LabCorp also provided blood draw and processing equipment, as well as a wall sign for the area where the LabCorp phlebotomist worked.

253. LabCorp placed a specimen collection box outside Dr. Miller's office, which would be emptied by another LabCorp employee according to a LabCorp-determined pickup schedule.

1. LabCorp's Conspiracy with Both HDL and Singulex to Violate the AKS

254. At the end of 2009 or the very beginning of 2010, after BlueWave, Carnaggio and Dent began marketing HDL's services, Dr. Miller switched from Berkeley to HDL. From 2010 until September 2011, HDL and Singulex supplied Dr. Miller's office with a centrifuge. This

centrifuge was used by the lab companies Dr. Miller used during that time period, including LabCorp, Executor, and Solstas.

255. In early 2011, LabCorp installed its own lab technician, Carletha Harris, in Dr. Miller's office. From that time until at least July 2013, LabCorp provided Dr. Miller with free blood draw and blood sample processing services for all referrals for clinical laboratory testing, including referrals to HDL and Singulex, as well as to LabCorp.

256. A recent LabCorp advertisement for a Patient Service Technician Specialist ("PST"), or phlebotomist, in the Charlotte, North Carolina area includes the following requirements for Harris' position: phlebotomy certification; completion of an approved phlebotomy training course; two years of experience as a patient service technician/phlebotomist; and proficiency in blood collection by venipuncture and urine collection; and use of LabCorp's technology (including "electronic reporting"). LabCorp's PSTs perform blood collection and processing, as well as packing and shipping of specimens.

257. Harris was paid by LabCorp to perform blood draws and to process blood samples for patients referred by Dr. Miller to Defendant LabCorp, HDL, and Singulex.

258. Harris worked in this capacity for several years. When Dr. Miller changed office locations on October 3, 2011, LabCorp technician Harris and her equipment moved with Dr. Miller to his new practice location. LabCorp always provided the following blood draw equipment to Dr. Miller's office (before and after the move): draw chair; LabCorp computer; copier; refrigerator; and blood draw supplies (needles, butterfly bandages, alcohol pads, etc.). When Dr. Miller moved his practice in the fall of 2011, LabCorp also supplied Dr. Miller's office with a centrifuge.

259. While the mere placement of the LabCorp technician in Dr. Miller's office would not, according to the 1999 HHS-OIG Fraud Alert, serve as an inducement prohibited by anti-

kickback statutes, the AKS was implicated when Defendant LabCorp's technician performed tasks that were the responsibility of the physician or his staff.

260. Here, according to HDL and Singulex arrangements and literature, HDL and Singulex paid Dr. Miller handsomely to perform "processing services" for blood samples drawn on patients referred to HDL and Singulex for testing. These HDL and Singulex processing services were purportedly the responsibility of Dr. Miller's staff. In reality, LabCorp paid Harris to perform nearly 100% of the processing services for all patient blood samples, including those destined for HDL and Singulex laboratories. This scheme to provide free processing services to Dr. Miller implicated AKS.

261. HDL and Singulex were aware of and encouraged this improper arrangement between Dr. Miller and LabCorp as it aided their business model, which required that blood is drawn in the physician's office in order to create the illusion that the kickback payments were fees to compensate the physician for blood draw and "processing" services.

a. LabCorp's Knowledge of HDL and Singulex Kickback Violations

262. Since at least the spring of 2010, LabCorp knew that HDL and Singulex were providing illegal inducements in the form of above-market "draw fees" or "P&H fees" to referring physicians and physician practices.

263. For example, correspondence between LabCorp executives, managers, and employees show that LabCorp knew or should have known that its physician practices were receiving illegal inducements from HDL and Singulex in exchange for referrals.

264. At the same time, LabCorp, through its employees and managers, acknowledged that the company should not be providing free blood draw and /or processing services for blood samples referred to HDL and Singulex by physicians in exchange for above-market draw fees or

P&H fees.

265. For example, on April 23, 2010, LabCorp employee Chris DiBiasi corresponded with Joan Atkins, then LabCorp's Divisional Compliance & Safety Manager, Winston-Salem, North Carolina. In his email, DiBiasi highlighted laws prohibiting the practice of paying physicians "draw fees which exceed fair market value could be considered an inducement. There are several smaller labs competing in our market offering \$20 per patient draw fees to clients." Rather than reply in writing, Atkins stated that she would discuss it orally over the telephone.

b. LabCorp Knew that Paying Above-Market Draw Fees Was Fraud

266. LabCorp knew that paying draw fees (or "processing and handling fees") in excess of \$3 was above fair market value. For example, in an email exchange dated June 28, 2010, Bill Merriman, LabCorp's Regional Manager, Specialty Manager, Atlantic Division (covering Maryland, Washington, D.C., Virginia, North Carolina, and South Carolina) Atkins, and Susan Whisnant, KAE (Raleigh, North Carolina) discussed a \$5 draw fee offered by Millennium Labs to a LabCorp client. Merriman referred to a discussion with another LabCorp employee who "says that this is non-compliant to offer draw fees above \$3." He asked Atkins if "this in the red compliance booklet anywhere?" Atkins responded: "Refer to Section 7 of the Little Red Book. If we were to pay, then it would be at fair market value which is \$3."

267. Throughout 2010, LabCorp employees around the country continued to circulate intelligence about bogus "draw fees" current and former Berkeley Heart Lab representatives were paying to referring physicians in exchange for blood specimens. LabCorp's compliance personnel responded by circulating established OIG guidance that these practices violate the federal AKS.

268. On September 2, 2010, a LabCorp KAE from the Raleigh, North Carolina area reported to Atkins that "HDL Labs" was "a lab out of VA. They are paying accounts \$20 draw fee

for their work.” When the KAE asked if the \$20 draw fee was legal, Atkins replied: “Are you somewhere that I can fax you the government’s opinion on this? And yes, they state it clearly implicates the Anti-Kickback statute.”

269. HDL’s practice of offering physicians inducements of \$20 draw fees and no balance billing to patients was confirmed just two weeks later. On September 16, 2010, Adrienne Overbay, a LabCorp Regional Manager of Business Development (“RMBD”) reported to Kathy Woodcock, Vice President of Managed Care, and Traci Butler, then a Vice President at LabCorp: “Here is some info on HDL. They are offering \$20 draw fees and no balance billing to patients. This talks about billing procedures, sounds a little funny to me.” Woodcock responded on December 10, 2010, and asked for Overbay to “send some of this documentation again, like their test request form and panel list.”

270. LabCorp communications from 2010 to 2012 show that LabCorp knew that HDL and the founders of its marketing company (Dent and Johnson) were sued by competitor Berkeley Heart Labs for using its customer lists to convert Berkeley users to HDL. LabCorp also knew that both Berkeley and HDL offered above-market draw fees to induce physician referrals.

271. For example, on October 5, 2010, Ryan Livingston, a senior marketing executive with LabCorp based in Scranton, Pennsylvania wrote to Tony Mei, LabCorp’s Compliance Officer, Northeast Division: “Carla and I have noticed some shady activity in your area with regards to the marketing practices of the Berkeley Heart Labs reps... it appears this lab is paying ‘draw fees’ to physicians who send specimens to this lab. Is this compliant? Have you heard of this from other regions in the northeast regarding this lab?” Mei responded: “Anything you might be able to get about this please send to me. I have attached an [sic] summary from the OIG about this. If you find out that this in fact the case, could help you combat it.”

272. By October 2010, LabCorp business development teams were working with others, including Liposcience, to “target” physician accounts in South Carolina that were referring patients to HDL.

273. On October 11, 2010, Overbay and LabCorp executives responded to news of HDL kickbacks by circulating LabCorp’s “test number equivalent for HDL.” Butler instructed LabCorp sales staff to “sell against HDL...we will discuss at our monthly meeting.”

274. LabCorp executives knew in May of 2012 that Quest had informed physician practices that they would not draw for HDL because they saw the payment of \$20 as a violation of Stark laws.

275. LabCorp’s employees in the Wilmington, North Carolina area acknowledged in June of 2012 that Dr. Miller had shifted his Berkeley referrals with HDL, that the LabCorp employees were providing phlebotomy services for Dr. Miller’s referrals to both HDL and Singulex.

276. In August 2012, in an exchange with Eric Feldman, LabCorp’s Vice President and General Manager of the Atlantic Division requested that Atkins, the divisional compliance officer, provide a document that could be shared with LabCorp’s phlebotomist and the office manager at a LabCorp physician practice customer. Atkins responded: “The only thing we can provide is federal regulations regarding ‘free services.’ These reqs. should be in the red books that I provided to all the sales staff.”

277. During 2013, LabCorp continued to discuss both internally and externally with customers that specimen collection services for physicians who were receiving draw fees or P&H fees from HDL or Singulex were receiving “remuneration” for referrals.

c. Leakage Reports: LabCorp Knows Physicians Who Referred to HDL and Singulex

278. Since before June 2010, LabCorp received so-called “Leakage Reports” from insurers, including Cigna, UHC, and Humana. Insurers who track leakage include managed care plans, including Medicare Part C plans and Medicaid managed care plans.

279. Leakage Reports are detailed lists of specific patient referrals by physicians to laboratory providers that were “out-of-network” for the insurer’s patient population. These tests by out-of-network labs are usually more expensive than network labs would charge because the insurers negotiate reimbursements with their network providers.

280. Leakage Reports include the following data that comes from actual claims submitted to the insurer: the patient; the referring physician and/or physician practice; the date of referral; the out-of-network lab; and the reimbursement by the healthcare provider.

281. The reason that LabCorp utilized “Leakage Reports were to: 1) police its customers’ compliance with using in-network labs; and 2) monitor which customers were referring patients to competitor labs for tests that could be performed by LabCorp.

282. HDL and Singulex were out-of-network providers for most, if not all, healthcare insurers. The Leakage Reports provided LabCorp with both the volume and the value of referrals to HDL and Singulex.

283. Beginning in at least June 2010, LabCorp received Leakage Reports that identified the LabCorp physician customers that had referred patients to HDL and Singulex.

284. The physicians identified in the Leakage Reports had patients who were covered by both government healthcare programs as well as commercial insurance policies. For example, many of the patients listed in the Leakage Reports were covered by Medicare managed care (Part C) programs, as well as traditional Medicare fee-for-service (Part B), Tricare, and other federally funded healthcare programs. The Leakage Reports also identified patients who were covered by

commercial insurers based in California or Illinois.

285. For example, in a September 2010 email, Pam Williams, a Managed Care Executive at LabCorp in the Goldsboro, North Carolina area wrote to Overbay, LabCorp's Regional Manager of Business Development, and others regarding a CIGNA Leakage Report, which identified providers who were referring to HDL.

286. Overbay and other managers and executives at LabCorp had been aware for months that HDL was paying above-market draw fees of \$20 and offering zero-balance billing to induce referrals.

287. In late November 2011, LabCorp executives, including Williams, discussed with insurers, including UHC, the insurer's expenditures for tests referred to non-participating labs, including "main driver" HDL. The discussions included LabCorp's report of "questionable practices" of paying physicians "\$25 or more for a specimen collection," which becomes a "revenue generating opportunity" for the physician.

288. From 2010 until at least mid-2014, LabCorp executives were aware of the nationwide scope of referrals to HDL and Singulex by LabCorp customers, the inducements paid by these competitor labs, and the threat to LabCorp business these inducements posed.

289. For example, 2011 LabCorp business plans written in December of 2010 acknowledged that competitor HDL was a threat to LabCorp business because HDL provided customers with "\$20 draw fees" and wrote off bills.

290. LabCorp's managed care executives working from corporate headquarters circulated insurers' Leakage Reports to executives and managers in every LabCorp region throughout the country.

291. LabCorp also used the insurers' Leakage Reports to systematically gather data

regarding the reasons physicians referred their patients to out-of-network labs (including HDL and Singulex). Through this data-gathering, LabCorp tracked competitor practices, such as payment of above-market draw fees and zero-balance billing as tools to induce referrals.

292. LabCorp used the external Leakage Reports received from insurers (Cigna, UHC, Humana, etc.) to create internal Leakage Reports. LabCorp's internal Leakage Reports included a wealth of data for each referring physician who was sending tests to LabCorp's competitors including: LabCorp Division, LabCorp Account Number; LabCorp Account Name; referring physician's NPI; referring physician's name; billing lab's tad identification number ("TIN"); billing lab's name; LabCorp quarterly revenue from the physician; LabCorp previous and current quarterly accessions from the referring physician; physician's specialty; previous quarter; Aetna, Cigna, ad Humana quarterly revenue; and leakage claims for the period (month or quarter).

293. LabCorp used the market intelligence gathered from Leakage Reports and other information from private insurers to defend against competitive practices of HDL and Singulex.

294. These actions included circulating the identities of physicians referring to HDL and Singulex in order to obtain intelligence regarding the reason why the physicians referred to these out-of-network providers. For example, LabCorp's internal Cigna Leakage Report from December 2012 identified multiple physician customers who intended to keep referring to HDL in order to collect the draw fee inducements.

295. LabCorp's internal Leakage Reports were disseminated to KAEs, RMBDs, and Senior Marketing Executives ("SME,") to educate them regarding their accounts, particularly the business lost by LabCorp to competitors.

296. The Leakage Reports were available electronically for LabCorp employees to follow up with customers. Entries in the internal LabCorp Leakage Reports were mandatory, and

the completed internal Leakage Report was sent to LabCorp corporate each month. In turn, LabCorp provided a “response file” to insurers. The insurers would then assist LabCorp’s leakage efforts by contacting providers on the leakage lists. LabCorp saw the Leakage Report process as an opportunity to increase its revenues by redirecting “leaked” business to LabCorp.

297. The internal LabCorp Leakage Reports included customers from every region in the country. For example, on a Leakage Report covering claims data for October to December 2013, Dr. Miller is identified as referring an average of 39 patients per month to LabCorp competitors. The same report identifies the LabCorp marketing executives assigned to Dr. Miller’s account: Leanne Preslar, SME; and Angela W. King, RMBD.

298. LabCorp’s internal Leakage Reports for October to December 2013 also identify providers in California who referred patients to HDL and/or Singulex. For example, a physician in Santa Clarita, California referred an average of 157 patients monthly to HDL during that time period.

299. Through its internal Leakage Reports, beginning in 2010, LabCorp systematically gathered intelligence from across the country that HDL and Singulex were receiving referrals in exchange for above-market “draw fees” and “P&H.”

300. For example, LabCorp used internal Leakage Reports and other communications to provide information to LabCorp corporate executives, including the reasons for lost business, the sales team’s efforts to redirect the business back to LabCorp, and the number of accessions per day or per week lost to competitors (including HDL and Singulex).

301. LabCorp employees discussed in November of 2010 that HDL’s payment of draw fees or processing fees was “an unfair advantage” for competitor HDL. Although there were discussions of leveraging an article about another lab company (Ameritox) that was fined for

providing a free \$5 urine testing cup as an inducement in order to sway customers away from HDL, the LabCorp employees acknowledged that their customers would not care until an enforcement action set precedent.

302. From at least mid-December 2010, LabCorp conducted regular, high-level meetings with insurers, including UHC, to discuss LabCorp's efforts to identify the physicians who referred patients to HDL and Singulex and the reasons for these referrals. LabCorp called this "UHC Leakage Tracking."

303. In February 2011, entries in LabCorp's internal Leakage Reports referenced the growing problem of referrals to HDL and the central role played by draw fee inducements. For example an entry dated February 9, 2011, in LabCorp's internal CIGNA Leakage Report stated: "Need CIGNA assistance as these clients are being paid by HDL a handling fee between \$15.00 to \$25.00 and are unwilling to give this revenue stream up." The report identified "lost business" from 18 LabCorp customers.

304. On or about March 21, 2011, LabCorp executives on the Atlantic Leadership Team Call discussed that HDL had become "the largest leakage lab by far...\$1.32 million and over 22,000 units in Q4 2010." It was also well known to LabCorp that "HDL is paying provider[s] as much as \$20 for collections." At that time, LabCorp had already "asked CIGNA for additional support at local and corporate level."

305. Other March 2011 communications show that LabCorp was using its internal Leakage Reports to "eradicate" HDL from its regions.

306. In June of 2011, competition from HDL was discussed among LabCorp employees in Mississippi (the Southeast region). They referred to HDL as a "spinoff" from Berkeley that offered physicians draw fees that "seems like an inducement," and that LabCorp phlebotomists

(including IOPs) were being asked to draw the HDL samples for LabCorp customers receiving the inducements.

307. In keeping with LabCorp's and insurers' efforts to redirect business from out-of-network providers (including HDL and Singulex), on November 9, 2012, Dr. Miller received a letter from Aetna directing him not to refer his Aetna patients to HDL, which was an out-of-network provider. Internal documents show that similar letters had been sent by Humana and Cigna in March of 2012.

308. LabCorp's internal Leakage Reports included a "Redirection Report" for recapturing lab tests referred to a competitor during a particular time frame. For example, in August 2011, LabCorp circulated an internal Leakage Report that included information on UHC leakage that showed physician customers in every division were referring patients to HDL. The sales team circulated the report in an email discussing the company's "Redirection update-July campaig [sic] and WINS tracking for May and June."

309. In January 2012, Tina Losinger, LabCorp Managed Care Executive in Texas (Mid America Region) emailed RMBDs Kathy Shannon and Kyle Schrier, attaching Humana leakage data: "Humana wants to focus leakage redirection efforts on Avee Labs (drug testing) and Health Diagnostic Laboratory. I am attaching a spreadsheet with four HDL targets in Houston, two in each of your regions."

310. LabCorp created sophisticated Leakage Reports which detailed LabCorp physician customers who were leakers who "overlapped," by appearing on more than one insurer's Leakage Reports.

311. Since at least 2008, LabCorp had tracked the courtesy draws (non-LabCorp draws) performed by its IOPs and PSCs. LabCorp tracked both HDL and Singulex draws performed by

its phlebotomists for its physician practices. For example, during the week of May 25, 2012, the LabCorp phlebotomist at one practice in South Carolina provided blood draw and processing services for 62 Singulex specimens and 61 HDL specimens.

312. For the August 2013 time frame, LabCorp's Leakage Report for the Mid America Region included a redirection report with data on competitor Singulex (94 physician NPIs associated with 197 claims, 1,335 units billed, and "raw data unit volume" of 3,005).

313. LabCorp continued to receive insurers' Leakage Reports and create internal Leakage Reports until at least June 2014. According to the LabCorp internal Leakage Report for June 2014, a LabCorp customer in Texas had referred at least 50 Humana insureds to out-of-network lab HDL.

d. LabCorp Also Received *Ad Hoc* Reports of HDL and Singulex Kickback Schemes

314. In addition to Leakage Reports, LabCorp also monitored which physicians were referring to competitor labs through its own employees' interactions with the physician customers and their staff. This *ad hoc* gathering of information by LabCorp occurred throughout the relevant time period.

315. In January 2011, LabCorp managers, including Frances Malik, in Rock Hill, South Carolina, and Dana Kay, a KAE in North Carolina, discussed the fact that LabCorp technicians in a physician practice were processing ("spinning and bagging") so many HDL specimens that the patient wait time for phlebotomy services was being negatively impacted.

316. In February 2011, Joyce Glasgow, LabCorp's Compliance/EHS Manager in Alabama, received additional intelligence from Michael Herndon, a RMBD in LabCorp's Southeast Region, that a physician customer was referring patients to HDL in exchange for \$27 per test. Glasgow provided this information and asked Atkins what she knew about HDL.

Incredulously, Atkins, who had received information about HDL kickbacks for nearly a year, responded that she knew only the name, but nothing more.

317. In June 2011 LabCorp employees continued to report that LabCorp “competitor” HDL was paying LabCorp’s physician customers for “drawing” HDL samples, even though LabCorp phlebotomists were doing the work. Glasgow confirmed that this was “an inducement.”

318. In late 2011 and 2012, LabCorp continued to receive reports from the field that its ability to compete was impacted due to HDL’s and other labs payments of inducements disguised as P&H fees.

319. In March of 2012, LabCorp sales employees were asked to rank competitors “according to their relative presence/aggravation for your division.” The West division, which included Denver, Colorado, replied that HDL was the No. 1 problem, due, in part, to paying draw fees of \$20 to \$30.

320. In August of 2012, Brett Sovey, LabCorp’s Vice President of Sales - Phoenix, Arizona wrote to Bob Nelson, LabCorp’s Senior Vice President - Dallas/Ft. Worth regarding the status of efforts to convert Cigna leakage. Sovey noted that HDL was paying LabCorp clients \$25 per draw, that clients were unwilling to give up that revenue, and that some clients were paid \$500 per day by HDL.

321. Nelson later noted to Chris Johns, RMBD: “there could be a major compliance problem when the doctor gets 25 bucks for a draw we do.”

322. In 2013, LabCorp executives issued company-wide requests for marketing research on competitor activities, particularly, “competitor laboratories potentially reimbursing physicians to draw their own patients.” LabCorp asked that employees provide the “name/location of the account and the amount per draw.”

323. In response, for example, between January and May of 2013, LabCorp employees in the Western Division discussed intelligence they had gathered on HDL inducements. Jenise Jeppson, LabCorp's RMBD in the San Francisco, California area, discussed with her divisional compliance and privacy officer, Kelleigh Barrigan, who was based in Washington state, Cameron Carrozza, a KAE based in Sacramento, California, and Tod Brett, an area director of business development based in Boulder Creek, California, discussed several LabCorp physician accounts that received money to draw and HDL specimens. The group then referenced "Section 8 of the Little Red Book of Compliance to highlight the OIG interpretation of remuneration for specimen collection," and the fact that this conduct constituted a kickback. Jeppson continued to share this type of intelligence on HDL payments for specimen collection through at least July 2013. The group even referred to HDL's services as "frivolous testing."

e. LabCorp's Knowledge Revealed: Two Requests for OIG Fraud Alerts Against HDL and Singulex

324. After gathering intelligence regarding kickbacks paid by HDL and Singulex to its customers, in recognition of the fraudulent nature of the payments, in April 2012, LabCorp executives asked counsel to draft a request for a fraud alert against its two competitors.

325. The 2012 deadline to submit the request had passed, so LabCorp waited for the next submission period in 2013. In early 2013, LabCorp submitted its first request for a fraud alert.

326. In early 2014, LabCorp submitted a second request for a fraud alert against HDL and Singulex.

327. In nearly identical requests, LabCorp described the two companies as "bad actors" and identified their bogus "draw fees" and "P&H fees" as fraud, while at the same time they were conspiring with them to get their claims paid. LabCorp specifically referred to HDL and Singulex offering physicians "inflated payments for collecting and processing specimens" despite "clear

OIG warnings since at least 2005.”

328. Ultimately, in June 2014, OIG issued a Special Fraud Alert in response to requests penned and submitted by LabCorp since 2012.

329. Only then did LabCorp dampen its efforts to collaborate with HDL. Now that its competitors’ (HDL’s and Singulex’s) kickback-fueled growth could be stunted or reversed by OIG’s reminder of the illegality of inflated payments for specimen collection and processing, LabCorp issued, for the first time, company-wide “talking points” directing the cessation of HDL and Singulex draws.

f. Quid Pro Quo for LabCorp: the Estimated Monthly Value (EMV) of LabCorp Tests Referrals by Physicians Referring to HDL and/or Singulex

330. To the best of Relators’ knowledge and information, LabCorp’s participation in the HDL and Singulex fraud resulted from a number of business objectives: 1) to gain or maintain the value of LabCorp customers’ referrals, described internally as the EMV of the physician account; 2) LabCorp was courting HDL from early 2011 to either acquire or invest in HDL in order to remove HDL as a competitor; and 3) LabCorp courted HDL and Singulex, in part because LabCorp made millions of dollars from business with HDL and Singulex between the end of 2010 and early 2015.

331. From early 2010 until at least mid-2014, Defendant LabCorp has provided blood draw and processing services for physicians, including Dr. Miller, who then referred their patients to HDL and Singulex.

332. By early 2011, LabCorp responded to news of HDL and Singulex inducements by establishing a policy of drawing for HDL or Singulex as long as the physician had also referred the patient to LabCorp for testing.

333. For example, on January 16, 2011, Whit Alexander, a KAE in the Mid-Atlantic Division wrote to compliance employee Joan Atkins regarding a discussion they had had a week earlier at a meeting regarding a physician receiving \$17 per blood specimen provided to HDL and wanted LabCorp phlebotomists to package the specimens for him. When Alexander asked for the section in LabCorp's compliance book that addressed the situation, Atkins replied: "Duties of PST as well as the offering of anything of value is considered an inducement and violation of the Stark laws."

334. Ten days later, on January 26, 2011, during an email exchange. LabCorp employees in the Mid-Atlantic Division, (including Whitman, his Vice President and General Manager, and his RMBD) discussed a customer who had asked LabCorp's phlebotomist to draw and process HDL referrals for which physician's practice was receiving \$20 to \$30 per patient. They also discussed similar payments in LabCorp's Charlotte, North Carolina market for HDL tests that cost \$2,000, and compliance concerns about LabCorp's services being "construed as an inducement." LabCorp's solution was to draw the HDL tests as long as there were tests coming to LabCorp. They also discussed negotiating a draw fee of \$5 or \$6 for the physician to pay LabCorp, thus ensuring that the physician customer still received an inducement of \$24-\$25 per referral (\$30 minus \$5 or 6).

335. Each time physicians, including Dr. Miller, referred a patient for HDL and Singulex testing, they also referred the patient to LabCorp for additional tests. For example, Relators observed that Dr. Miller also referred patients to LabCorp both during and outside of HDL and Singulex testing episodes.

336. Although LabCorp had knowledge that its phlebotomists were providing draw and processing services for physicians receiving HDL and Singulex kickbacks, at no time during 2010

or 2011 did LabCorp issued a company-wide compliance directive instructing its employees to stop drawing and processing HDL and Singulex specimens.

337. LabCorp's internal documents show that by January 2012, LabCorp phlebotomists were instructed that they could draw for HDL and Singulex if there were also referrals being made to LabCorp.

g. For LabCorp, the EMV (Estimated Monthly Value) of Referrals to Labcorp Overrides Compliance

338. In March 2010, Kelly Saieed, a KAE based in Greenville, North Carolina, explained to Overbay, a LabCorp Regional Manager of Business Development: "Dr. Gay met with Millinium [sic] labs and they offered to rent the space that our IOP uses. Can we offer to rent that space? I told Marcia I would call her as soon as I could find something out. Dr. Gay is all about the \$\$\$\$\$. Just FYI." At the time, Millennium Labs was a LabCorp competitor. Overbay responded: "EMV? There are stark regs around this. We would have to open to outside etc. Look in your red compliance book." Kelly Saieed replied: "EMV:23k...I will look in the red book."

339. This pattern continued into 2011. For example, in July of 2011, when a customer wanted LabCorp to draw HDL samples, the discussion focused on the EMV of the business at risk if LabCorp did not provide the phlebotomy services for HDL draws.

340. In August 2011, when another LabCorp physician customer requested that the LabCorp PSC providing draw and processing services for competitor lab tests, including HDL, LabCorp approved the request after discussing the \$35,000 EMV of business for LabCorp, and the fact that the practice was the impetus for establishing the PSC.

341. In spite of the company's clear knowledge that HDL and Singulex were paying kickbacks, LabCorp employees were instructed to provide free phlebotomy services. This was in violation of both internal policy and federal statutes and regulations.

342. For example, Defendant LabCorp never charged or attempted to charge Dr. Miller for performing either blood draws (blood collection) or blood processing services for patients referred to HDL or Singulex until sometime in 2012.

343. LabCorp has provided free blood draw and processing services to Dr. Miller's patients who were referred to HDL and Singulex in exchange for referrals to LabCorp.

344. LabCorp's failure to charge Dr. Miller is mirrored in other LabCorp practices around the country. For example, in February 2013, when Alexander, another KAE in South Carolina, was asked if he had discussed HDL's "draw fee" with a physician practice, he replied that the regional sales manager, Angela [King] had advised him "to draw and not charge" the physician.

345. LabCorp internal documents show that LabCorp knowingly facilitated HDL and Singulex kickbacks in order to gain or retain LabCorp business. For example, on May 25, 2012, Melissa Fuller, LabCorp manager in South Carolina, wrote to KAE Alexander that if LabCorp phlebotomists won't perform specimen collection services for outside labs (including Singulex and HDL), the physician account will end its contract with LabCorp.

346. LabCorp placed revenue concerns ahead of assisting insurers to eliminate leakage to HDL and Singulex. In an April 2013 email, KAE Carolyn Stokes wrote to Emily Dickey, RMBD in the Houston, Texas market, that UHC was being "aggressive" in sending letters to clients about referring patients to HDL. Dickey replied that if UHC's tactics resulted in all of LabCorp's accounts using HDL being kicked out of UHC's network, LabCorp "would be losing some big business!"

347. On May 22, 2012, Sonya White, a LabCorp phlebotomy services technician supervisor based in Houston, Texas, wrote to Mary Davis, her regional compliance officer, and

Stover. White noted the LabCorp policy against courtesy draws, and added: “I know we are doing them everywhere. I’m not trying to open a can of worms....” Davis replied that the problem was “the Sales Team are telling our PST’s to draw for physicians for free.”

348. In a June 11, 2012, email Matt Neighoff, LabCorp Corporate Vice President of Sales and Development, tells Todd Hooper, Vice President, and Overbay that phlebotomists (IOPs or PSCs) are drawing HDL specimens and that phlebotomy supervisors should speak to the LabCorp sales team before telling a physician that the LabCorp phlebotomists (IOPs or PSTs) will not draw HDL specimens.

2. LabCorp Demands a Fee If Dr. Miller Does Not Provide the Quid-Pro-Quo (Referrals) to LabCorp

349. Sometime in 2011 or 2012, Jason Erxleben, KAE, became the LabCorp marketing representative responsible for sales to physicians in the Florence, South Carolina area, where Dr. Miller’s office is located.

350. From that time until late 2012, Erxleben has provided ongoing customer service to LabCorp customer, Dr. Miller.

351. In that capacity, Erxleben last visited Dr. Miller’s office during September 2012.

352. Sometime before September of 2012, Erxleben provided lunch for Dr. Miller and his staff. At that time, he requested that Dr. Miller refer patients to LabCorp for a Lipid Cascade and not to HDL for a lipid panel.

353. In September of 2012, Dr. Miller told Erxleben that he refused to stop referring patients to HDL for the lipid panel. Erxleben then informed Dr. Miller and/or Dr. Miller’s office manager that LabCorp wanted to charge Dr. Miller a \$5.00 fee per patient. Erxleben made it clear, however, that LabCorp was willing to continue to provide Dr. Miller with free blood draw and processing services for referrals to HDL and Singulex as long as Defendant LabCorp also received

referrals from Dr. Miller for lipid testing.

354. Relators believe that Defendant LabCorp had access to and closely tracked Dr. Miller's referral data, including testing referrals to HDL and Singulex. The LabCorp phlebotomy technicians, including Harris, received Dr. Miller's LabCorp requisitions which identified each tests were referred to LabCorp, HDL, and Singulex. It is clear from Erxleben's statement that, even though he was not present to review each paper requisition or to observe all blood drawn and processed for referrals to LabCorp, HDL, and Singulex, he obtained Dr. Miller's referral information for LabCorp, HDL, and Singulex tests.

355. Erxleben, used referral data to enforce LabCorp's *quid pro quo* (free phlebotomy services for HDL and Singulex specimens in exchange for referrals to LabCorp).

356. As stated above, the agreement between BlueWave and Singulex authorized BlueWave to pay independent lab companies, such as LabCorp, to draw or process blood samples for Singulex.

357. Relators allege upon information and belief that BlueWave had an agreement with HDL which, like the agreement with Singulex, authorized BlueWave to pay independent lab companies, such as LabCorp, to draw or process blood samples for HDL. However, Relators do not believe that BlueWave paid independent lab companies, such as LabCorp, to draw or process blood samples for patients Dr. Miller refers to HDL.

358. LabCorp reports for many of Dr. Miller's patients whose blood was drawn on December 10 and December 11, 2012, contain the following notation in the "additional information" section: "DRAW FEE TO HDL." These patients' blood samples were drawn while the regular LabCorp technician, Harris, was on vacation.

359. Relators believe that, for a day and a half (December 10 and half of December 11,

2012), the replacement LabCorp technician noted in the LabCorp computer a relationship between the draw fee for these patients and HDL.

360. These documents support the conclusion that LabCorp knew that physicians, such as Dr. Miller, were referring patients to HDL as a result of HDL's inducements.

3. LabCorp's Inducement to Dr. Miller Causes Unnecessary (Duplicative) Testing

361. Dr. Miller regularly referred patients to LabCorp for tests that were in part duplicative of the testing services he referred to HDL. For example, on November 6, 2012, Dr. Miller referred patient B.B. to HDL for, among other things, a lipid-panel test that included tests for Total Cholesterol, LDL-Cholesterol, HDL-cholesterol and Triglycerides. Dr. Miller also referred B.B. to LabCorp for the same tests on the same day. Dr. Miller refers patients to HDL and to LabCorp for duplicative tests as a standard practice.

362. LabCorp received referrals from Dr. Miller for tests for the following patients who are beneficiaries of government healthcare programs that are duplicative of referrals to HDL:

Patient	Insurance	Date of LabCorp Report	Date of HDL Report
DDF	Medicare, Medicaid	5/5/2011	5/13/2011
EAD	Medicare, Medicaid	8/8/2011	8/11/2011
LB	Medicare, TRICARE	12/13/2012	12/22/2012

363. LabCorp provided free blood draw and processing services to Dr. Miller, at least in part, in exchange for Dr. Miller's referrals to LabCorp. Some of the LabCorp tests were duplicative of laboratory testing referred to HDL.

4. LabCorp Knew Its Tests Were Duplicative

364. To have the LabCorp technician draw all of the blood samples for each patient, Dr.

Miller wrote all of the clinical laboratory tests for his patients on the LabCorp requisition form. The LabCorp requisition has a space marked “other” where Dr. Miller or his staff hand wrote “HDL/Singulex.”

365. For example, the LabCorp requisition for Dr. Miller’s patient, LB, a Medicare (primary) and TRICARE (secondary) beneficiary, included the referral for “other” tests, “HDL/Singulex.” The same LabCorp requisition also included referrals to LabCorp for a lipid panel that is duplicative of one performed by HDL.

366. LabCorp knew when tests ordered by Dr. Miller and selected on the LabCorp requisition were duplicative of tests referred to HDL because the LabCorp requisition clearly shows both HDL and Singulex referrals, plus a number of referrals for LabCorp testing.

367. The LabCorp technician drew blood for all of the laboratory testing, including HDL, Singulex, and LabCorp. Based on the technical knowledge and experience required for LabCorp phlebotomists, the LabCorp employee knew or should have known when tests referred to LabCorp by Dr. Miller were duplicative of tests referred to HDL.

368. Defendant LabCorp also provided computers to their technicians, including Carletha Harris, the LabCorp employee/technician who performed blood draws and processing at Dr. Miller’s office. Relators believe that Defendant LabCorp tracked whether the patient was referred to LabCorp, HDL, or Singulex through computer entries or other means by the lab technician.

369. At least one purpose of the free phlebotomist services provided by Defendant LabCorp to Dr. Miller and other physicians who also referred patients to HDL and Singulex, was to induce providers to refer patients to LabCorp for clinical laboratory testing.

E. HDL, Singulex, and LabCorp Offer Significant Remuneration _____ (In Cash and In Kind) to Physicians for Referrals

370. HDL and Singulex created and maintained records of the illegal inducements they paid to Dr. Miller. In particular, HDL and Singulex recorded on a “Draw Log” for each patient referred by Dr. Miller, the name of the patient, the date of birth, the date of the referral, and payment to Dr. Miller for the referral. Singulex later changed the name of the referral log to “Process and Handling” log.

371. Whether called a “draw” log or “P&H” log, these referral logs were created in order to facilitate paying referring physicians based on the volume (number) of patients referred to HDL or Singulex.

372. Relators have reviewed the referral logs and other documents, including checks, showing substantial cash payments made by HDL and Singulex to Dr. Miller for patient referrals.

1. HDL Kickbacks: \$130,000-Plus

373. Between August 10, 2010, and May 19, 2011, Dr. Miller referred 1,611 patients to HDL. In exchange, HDL paid remuneration (kickbacks) to doctor Miller, at \$20 per patient, for a total of \$32,220.00 in just a nine-month period.

374. From January 2010 until July 2012, based upon Dr. Miller’s referral history, Relators estimate, based on 185 referrals per month, that HDL’s kickback payments to doctor Miller, at \$20 per patient referred, exceeded \$133,000. Dr. Miller has referred more than 200 patients per month to HDL.

2. Singulex Kickbacks: \$55,000-Plus

375. During the same nine-month period (between August 10, 2010, and May 19, 2011), and based on Dr. Miller’s practices, Dr. Miller referred 1,611 patients to Singulex. In exchange, the remuneration Singulex paid Dr. Miller, at \$10 per patient, was \$16,110.00.

376. Relators estimate that, based on 185 patient referrals per month, since July 2010, Singulex paid remuneration (kickbacks) to Dr. Miller, at \$10 per patient referred, in excess of

\$55,000. Dr. Miller has referred more than 200 patients per month to Singulex.

3. LabCorp Kickbacks: Full Time Phlebotomist Salary

377. In addition to the cash remuneration provided by HDL and Singulex, Defendant LabCorp provided referring physicians with free blood draw and processing services. At a minimum, Relators believe that the value of this “in-kind” remuneration to physicians such as Dr. Miller can be measured by LabCorp’s cost for the phlebotomist’s full-time salary, plus benefits.

378. In the alternative, LabCorp contracts provide for payment for phlebotomy charges according to a fee schedule. The 2011 LabCorp fee schedule indicates that LabCorp charges \$5.25 for venipuncture, and \$24.00 per hour for phlebotomist services (in addition to the draw fee) where more than 72 hours’ notice is provided and the services are not regularly scheduled.

a. LabCorp’s Second Reason to Facilitate HDL Referrals: From 2011, LabCorp Courted HDL to Acquire or Invest in HDL

379. Despite the fraudulent activity that LabCorp knew HDL and Singulex were engaging in, LabCorp tried to purchase HDL in mid-2011. HDL was not interested in selling to LabCorp at the time.

380. At the time, LabCorp’s Anil Asnani, Vice President, Strategic Planning & Corporate Development, was well aware of HDL’s fraudulent scheme to provide inducements to physicians in exchange for referrals.

381. From 2011 until 2014, LabCorp, through Asnani and Ben Miller, Executive Vice President for Business Development, continued to court Tonya Mallory, HDL’s founder and CEO, and to seek opportunities for collaboration between the two laboratory providers. Both Asnani and Miller reported to CEO King.

382. For example, in February 2013, before submitting its first request to OIG for a fraud alert against HDL, Mallory and LabCorp executives exchanged communications regarding a

“strategic partnership” between the two companies.

383. Days later, Mallory shared with Miller and Asnani: “Looks like we dodged a bullet today with Medicaid in Virginia. It may not be over, but it looks like a partial victory for today.”

384. During 2013 and 2014 LabCorp executives continued to pursue business relationships with and/or an investment in HDL. The LabCorp executives who met with Mallory included CEO King, Asnani, and Miller.

385. The communications between LabCorp and HDL’s CEO, Mallory, included the discussions regarding the use of LabCorp phlebotomists to draw HDL blood samples for referring physicians.

b. LabCorp Courted “Bad Actors” HDL (and Singulex)

386. As recited above, between January and June 2010, LabCorp was aware that HDL was inducing its physician customers with \$20 “draw fees.” LabCorp knew that it should not be providing phlebotomy services for HDL referrals.

387. At the same time, LabCorp continued to gather information on specific LabCorp physician customers around the country who were referring to HDL (and Singulex), both through systematic efforts from Leakage Reports and *ad hoc* reporting by account representatives and other employees in the field.

388. In spite of the company’s knowledge of HDL’s practice of paying referring physicians kickbacks, since at least the end of 2010, LabCorp pursued business relationships with HDL and Singulex. For example, from late 2010 until 2015, LabCorp performed tests for HDL. In all, LabCorp invoiced HDL for more than \$7.6 million. HDL made payments to LabCorp until March of 2015.

389. In mid-2011, LabCorp met with HDL CEO Mallory in order to discuss

collaboration with or the outright purchase of HDL's business.

390. By early 2012, LabCorp adopted a policy that its phlebotomists could draw for HDL and Singulex if there is also a referral being made to LabCorp.

391. During this same time period, LabCorp was communicating with commercial insurers, including UHC, Aetna, and Humana, that the company was taking action to redirect referrals away from HDL.

392. By June of 2011, both LabCorp and multiple private insurers, including UHC knew or should have been aware that HDL was providing illegal inducements to physicians in exchange for referrals.

393. Simultaneously, from April 2012 until February 2014, LabCorp executives directed the drafting and submission of requests for an OIG fraud alert aimed at HDL's payment of kickbacks. LabCorp called HDL a "bad actor" for paying above-market draw fees or P&H fees.

394. LabCorp was willing to turn a blind eye to HDL's fraud when it suited LabCorp's bottom line. For example, in October 2012, LabCorp business development managers asked: "HDL business practices aside, what are they doing in the KS, TX and AZ markets?"

395. LabCorp's pursuit of a close business relationship with HDL continued unabated through 2013. In February 2013, HDL and LabCorp enter into a formal Non-Disclosure Agreement ("NDA"), and LabCorp executives exchanged cell phone numbers in order to communicate orally with Mallory.

396. On February 26, 2013, while waiting for a call from Mallory regarding potential collaboration between LabCorp and HDL, LabCorp submitted its first request for an OIG fraud alert. In the request, LabCorp acknowledged that its potential collaborator, HDL, was a "bad actor" for paying "draw" or "P&H" fees in violation of the federal AKS.

397. Three days later, on March 1, 2013, top LabCorp executives, including Miller and Eric Lindblom, Senior Vice President of Esoteric Business and Specialty Sales, met with Mallory, Dent, Johnson, and others at LabCorp's headquarters in Burlington, North Carolina to discuss business opportunities between LabCorp and HDL. According to an executive summary of the meeting, the first "mutually beneficial" issue discussed was use of LabCorp's "Patient Service Centers – phlebotomists."

398. Days after senior LabCorp executives met with HDL top brass, another LabCorp executive, Robert Boston, communicated internally with LabCorp executives and managers, including Ben Miller, about LabCorp's work with UHC on "redirection strategies," which were aimed at "redirecting" physician referrals away from HDL and Singulex. The insurers and LabCorp were aware that referring physicians were being induced by above-market draw fees.

399. Later that month, and in mid-April 2013, Mallory and LabCorp executives discussed LabCorp's potential collaboration with and/or investment in HDL. The subjects included providing LabCorp's CEO King with information regarding HDL's investment bankers, the Cain Bros., as well as partnering between LabCorp and HDL on physician accounts.

400. By July 2013, HDL was sending more than \$100,000 a month in testing business to LabCorp.

401. A second high-level meeting between LabCorp and HDL executives was held at LabCorp headquarters in Burlington, North Carolina in August 2013.

402. On August 30, 2013, Mallory and other HDL executives travelled to LabCorp headquarters in Burlington, North Carolina for the third high-level meeting. LabCorp executives in attendance included King and Miller.

403. In September 2013, Miller informed Mallory that LabCorp had agreed to draw HDL

samples in a large account with a health system based in Baltimore, Maryland and extending south through Virginia into the Carolinas. In reality, LabCorp phlebotomists in many of these accounts had been drawing for HDL referrals since at least 2012.

404. During that same month, LabCorp executives and Mallory worked to set up another meeting between the two companies. King directed Miller to compile a list of areas for potential collaboration. Miller then reported to Mallory, in an email dated September 16, 2013, that he had prepared such a list.

405. Communications between LabCorp and HDL during October 2013 discussed the status of a NDA between LabCorp and HDL, as well as LabCorp's request for "high level information on revenue, volume and expense."

406. On November 5, 2013, LabCorp received a request from the Government for information related to phlebotomy services provided by LabCorp for Dr. Miller.

407. A meeting between King and Mallory that was scheduled to take place at HDL headquarters on November 21, 2013 was postponed.

408. LabCorp and HDL executives discussed rescheduling their meeting for January 24, 29, or 30, 2014. Miller was charged with contacting Mallory to "coordinate a date and the agenda."

409. In January 2014, LabCorp executives traveled to HDL headquarters in Richmond, Virginia for additional high-level meetings.

410. A month later, on February 26, 2014, LabCorp submitted a second request for an OIG fraud alert against HDL's practices.

411. During the spring of 2014, executives at LabCorp and HDL worked to schedule a high-level meeting to discuss LabCorp's potential collaboration with or investment in HDL. LabCorp executives met with HDL's investment bankers at the end of March 2014. During March

and April 2014, King and Mallory had several conversations during which they discussed plans for the next in-person meeting between the two of them.

412. On April 11, 2014, following the discussions referenced above, LabCorp made an unannounced increase (from \$5 to \$20) in the draw fee associated with 005587 - the code that was supposed to be used to bill for drawing non-LabCorp tests, such as tests referred to HDL. This price increase, if billed and paid by a LabCorp customer for each HDL draw, would remove the financial incentive for referring to HDL (as the customer would receive \$20 from HDL, but then pay the same \$20 to LabCorp).

413. In late April or early May 2014, LabCorp's King met with HDL's investment bankers, the Cain Bros. Specifically, King met with Robert J. Fraiman, President & CEO of Cain Bros., while both were attending the annual Health Evolution Partners ("HEP") Summit in Laguna Niguel, California. They met to discuss potential LabCorp collaboration with HDL.

414. In mid-May 2014, Jonathan Pritti of Cain Bros. communicated to Mallory and his colleagues that King wanted to meet with Mallory alone to discuss collaboration with and/or investment in HDL. Pritti suggested that Mallory e-mail King to arrange the meeting.

415. In May 2014, Overbay, who had been aware of HDL's practice of paying inducements for referrals since 2010, referred to LabCorp's collaboration with HDL as a "wild card."

416. In an email a month later, King recognized the precarious position that LabCorp had taken in pursuing a business relationship with HDL, while at the same time working with private insurers to redirect referrals away from HDL. King directed his business development team to proceed with caution in collaborating with or investing in HDL because it was a major "leaker" with UHC.

417. Years before, Mr. King had been personally involved in setting up a multi-billion dollar agreement between UHC and LabCorp. His reference to HDL being a “leaker” evidences Mr. King’s knowledge of the Leakage Reports received by LabCorp executives, which, for years, had identified LabCorp physicians who were referring out-of-network, including referrals to HDL and Singulex.

418. Despite these concerns, King sent an email to Fraiman regarding dates for King to meet with Mallory.

419. On June 25, 2014, OIG issued the fraud alert related to HDL and Singulex paying inducements to referring physicians. The OIG Fraud Alert can be found at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/oig_sfa_laboratory_payments_06252014.pdf.

420. Amazingly, two days after the OIG issued the fraud alert against HDL’s and Singulex’s practices, on June 27, 2014, LabCorp executives met in New York City with Cain Bros. to discuss potential collaboration with and/or investment in HDL.

421. On July 21, 2014, Mallory sent an email to King following their meeting on June 27, 2014. Mallory attached a proposed “Memorandum of Understanding between HDL, Inc. and LabCorp,” which described the relationship that King and Mallory “contemplate[d] between HDL, Inc. and LabCorp,” including the “goal of the relationship.” Mallory noted that she and King had discussed HDL’s need for LabCorp’s assistance in providing phlebotomy services and gaining “payer acceptance.”

422. On July 28, 2014, King communicated to Mallory, for the first time, that LabCorp was no longer interested in collaborating with HDL. In response to Mallory’s earlier email, King stated: “Thanks for the follow up. At this time we are not interested in pursuing this opportunity.”

423. Notwithstanding the above, LabCorp continued to do business with HDL and to bill HDL for testing it performed for HDL through March of 2015.

424. In September of 2015, LabCorp again showed interest in purchasing HDL, which was then in bankruptcy as a result of its fraudulent business practices. The LabCorp executive submitting the requisite paperwork was Asnani, LabCorp's Vice President, Strategic Planning & Corporate Development.

c. LabCorp Also Courted "Bad Actor" Singulex for Years

425. As early as 2009, Singulex was of interest to LabCorp executives, including CEO King. For example, in August 2009, King wrote an email seeking intelligence on competitor Singulex: "Know anything about Singulex?"

426. In 2010, LabCorp became aware that Singulex, like HDL, was paying kickbacks through above-market "draw fees" and/or "P&H fees."

427. LabCorp knew that phlebotomy services its employees provided for both HDL and Singulex referrals were inducements for physicians to refer patients to these labs.

428. As Singulex did not provide physicians with phlebotomists, it relied on independent labs such as LabCorp to draw and process samples referred by physicians. Many of these referrals were made by physicians who had been offered inducements through draw fees and/or P&H fees.

429. Beginning in at least the third quarter of 2010, Leakage Reports include references to LabCorp physician customers referring patients to Singulex.

430. Despite this knowledge, LabCorp phlebotomists continued to draw Singulex blood samples through 2011, 2012, 2013, and 2014.

431. In the spring of 2011, LabCorp began to pursue lost business from physicians across the country who appeared on the Leakage Reports as referring physicians for Singulex. These

referring physicians included Dr. Miller in South Carolina.

432. When the question of drawing for HDL or Singulex arose, LabCorp focused on the EMV to LabCorp of the physician account. LabCorp focused on revenue at risk if the company followed LabCorp's internal compliance rules, as well as federal statutes and regulations, which prohibited the facilitation of kickback payments.

433. For example, in July of 2011, LabCorp employees referred to a risk of losing an account worth \$25,000 per month ("EMV \$25K") if LabCorp refused to provide phlebotomy services for HDL or Singulex draws.

434. Throughout 2011, 2012, 2013, and 2014, LabCorp continued to carefully track the actual number of referrals by its customers to Singulex and it re-confirmed that physicians were receiving kickbacks from Singulex.

435. For example, a November 2011 report showed an account referring 105 patients to Singulex that month. Another LabCorp document from 2012 referred to the number of HDL and Singulex referrals by a LabCorp customer in a week.

436. By 2012, LabCorp entered into a contract with Singulex to perform some of the tests in the Singulex panel. This provided LabCorp with a direct benefit from drawing Singulex samples for referring physicians.

437. By early 2012, LabCorp had developed a similar policy for Singulex and HDL: the LabCorp phlebotomist can draw Singulex samples if there is also a referral coming to LabCorp.

438. However, at the same time, LabCorp was drafting a request for an OIG fraud alert against Singulex's payment of P&H fees to referring physicians.

439. By July 2012, LabCorp was submitting invoices to Singulex for tests it performed from the Singulex testing panels referred by physicians, including those receiving inducements in

the form of draw fees or P&H fees.

440. In November 2012, Singulex budgeted \$15,000 monthly for payments to LabCorp for tests it performed on the Singulex panel, including but not limited to the Lp-PLA2.

441. By early 2013, LabCorp and Singulex were collaborating to provide testing for employee health plans, including the 12,000 members of the “HIS” employee health program.

442. In the midst of LabCorp’s collaboration with Singulex, LabCorp was aware that HDL and Singulex were engaged in the same fraudulent practice of bribing referring physicians with above-market draw fees.

443. Robert Boston, LabCorp’s Strategic Director, noted in an email dated March 2013: “HDL-projected to be a \$60 million annualized spend.... Seeing a tandem marketing effort with Singulex as far as their field selling organization is concerned. As you know, resonating with practices through use of waiving/capping copays and paying of non-market draw fees.”

444. Even after LabCorp submitted its second request for an OIG fraud alert on February 26, 2014, LabCorp continued to collaborate with Singulex and to provide phlebotomy services associated with Singulex referrals by LabCorp’s physician customers.

445. LabCorp invoiced Singulex for performing tests initially referred to Singulex beginning in 2012 and continuing through 2014. During 2012 and 2013 alone, Singulex received invoices from LabCorp totaling more than \$277,500.

446. LabCorp continued to provide phlebotomy services for Singulex referrals through at least June 2014.

F. HDL, Singulex and BlueWave National Scheme: Inducing Referrals for Lab Tests

1. BlueWave’s Founders Deliver the HDL and Singulex Promotions: Fees for Patient Referrals

a. The National Scope of HDL’s Scheme

447. Upon information and belief, before their January 1, 2010, departure from Berkeley, the founders of BlueWave (Dent and Johnson) and HDL collaborated to develop a nationwide marketing program for HDL.

448. Relators allege upon information and belief, that HDL's offer of \$20.00 processing fees to referring physicians was approved by HDL as part of the marketing program delivered by BlueWave to all potential HDL customers nationwide.

449. HDL's product manual is called the "In Service Guide for Lab Partners" in recognition of the physicians who "partner" with HDL through compensation arrangements.

450. Upon information and belief, BlueWave's sales representatives offered the same cash inducements to many physicians (in addition to Dr. Miller) to induce them to refer patients to HDL for laboratory testing. For example, Relators allege upon information and belief that many physicians in North Carolina, South Carolina, and Georgia received the same promotional offer, namely HDL's offer of inducements that BlueWave made to Dr. Miller.

451. In the fall of 2012, Blue Wave's Dent and Carnaggio provided Dr. Miller with HDL's marketing materials for the EarlyCDT-Lung test, including a page of suggested ICD-9 codes. These same marketing HDL marketing materials and suggested ICD-9 codes for HDL's lung test are distributed by HDL representatives from Florida to Pennsylvania.

452. As stated above, Kyle Martel, one of the original BlueWave sales representatives, began promoting HDL and Singulex products in Florida in 2010.

453. In 2012, Martel and Charles Maimone, Jr. formed "C&K Healthcare Consultants." Maimone, who is based in New Jersey, is listed as the HDL representative on a sample HDL new customer form that was provided to a physician practice in Pennsylvania. HDL's new customer form was last revised in 2010.

454. Relators believe, and therefore aver, that Maimone promoted HDL and Singulex products in New Jersey and Pennsylvania, and that he used the same marketing materials and offers the same inducements that BlueWave, HDL, and Singulex had promoted from 2010 to 2014.

455. HDL's national marketing practices, as promoted by BlueWave, resulted in many physicians (in addition to Dr. Miller) receiving a \$20.00 per patient "processing services" fee each time a patient is referred to HDL.

456. Utilizing this model, BlueWave and HDL implemented a marketing program which resulted in illegal inducements being paid to referring physicians in all of the 45 states where HDL operated.

457. The national scope of HDL's inducement scheme is also supported by Mallory, who stated that HDL's business practices included obtaining W-9 forms from physicians as they become new customers. This W-9 form was necessary for HDL to issue 1099 forms reflecting the compensation arrangement that HDL has with many physicians throughout the United States. HDL paid physicians nationwide for "processing services."

b. HDL Induced Physicians to Switch Overnight

458. As former sales representatives for HDL's competitor, Berkeley, BlueWave's original sales representatives had access to information regarding physicians with robust practices and valuable referrals. For example, at the end of 2009, Dr. Miller was the number one prescriber of Berkeley tests in Dent's sales territory, which included North Carolina, South Carolina, and Georgia.

459. Just one week into 2010, after BlueWave (through its founder Dent, and Carnaggio) began promoting HDL testing, Dr. Miller stopped referring patients to Berkeley and started referring patients to HDL. Thereafter, HDL started paying Dr. Miller a \$20.00 per patient referral.

460. Relators allege upon information and belief that Dr. Miller is only one of many

former Berkeley customers who switched their referrals to HDL after BlueWave started promoting HDL clinical laboratory testing services. Relators further allege upon information and belief that, after they changed referrals to HDL, many other physicians received HDL's \$20.00 per patient fee for "processing services."

461. HDL's practice of offering and paying a \$20.00 per patient inducement to Dr. Miller continues today. HDL's practice of offering and paying a \$20.00 per patient inducement to other referring physicians is also ongoing.

G. BlueWave Delivers Singulex Offers of "Processing Fees"

462. In June 2010, BlueWave (through its founder Dent and Johnson, and sales representative Carnaggio) began promoting Singulex testing. By July 2010, Dr. Miller was referring nearly every patient to Singulex. Thereafter, Singulex started paying Dr. Miller a \$10.00 per patient fee. Singulex refers to these as fees for "processing services."

463. Relators also allege upon information and belief, that BlueWave facilitated an offer by Singulex to pay Dr. Miller a \$10.00 fee for each patient referred.

464. Relators allege upon information and belief that BlueWave's founders carried out promotional programs with Dr. Miller that were vetted and approved by Singulex for delivery to all potential Singulex customers in all states covered by Singulex and BlueWave promotional agreements.

465. Relators allege upon information and belief that, since June of 2010, Singulex and BlueWave used the same marketing practices throughout BlueWave's sales territories that they employed with Dr. Miller in order to induce many physician customers to refer their patients to Singulex.

466. Singulex's practice of offering and paying a \$10.00 per patient inducement to referring physicians throughout the country, including Dr. Miller, continued until at least June

2014.

1. BlueWave and HDL Grab Physician Referrals in Many States

467. The sales territory served by BlueWave's sales representatives Carnaggio and Dent while they worked at Berkeley, was North Carolina, South Carolina, and Georgia.

468. Beginning in January 2010, BlueWave, its principals, and agents marketed HDL testing services in many states, including: North Carolina, South Carolina, Georgia, Florida, California, Colorado, Louisiana, Missouri, Mississippi, New Jersey, New York, Texas, Tennessee, Virginia and Wisconsin.

469. In addition to Dr. Miller, many former Berkeley physician customers from across the United States stopped referring patients to Berkeley after BlueWave started promoting HDL testing. These physicians include: Dr. Thomas L. Jeffries of Raleigh, NC; Dr. Gerald M. Kovar of Tarzana, CA; Dr. Michael Rosemore of Hueytown, AL; and Dr. James Mensone of Greenville, SC.

470. BlueWave, Dent, Johnson, and HDL have promoted HDL products to former Berkeley physician customers in at least the following states: Alabama, California; Colorado; Florida; Kansas; Louisiana; Missouri; Mississippi; New Jersey; South Carolina; Texas; and Virginia.

471. HDL's national promotional program included offering potential physician customers "processing fees" for each patient referred to HDL.

472. Upon information and belief BlueWave's sales representatives offered the same cash inducements they offered to Dr. Miller to many physicians across the United States, including former customers of Berkeley as well as new targets, to induce them to refer patients to HDL for laboratory testing.

473. Relators allege upon information and belief that beginning in at least January of

2010, like Dr. Miller, many physicians throughout the United States referred patients to HDL and accepted HDL's offer of bogus "processing fees" in exchange for each patient referral to HDL.

474. Upon information and belief, beginning in at least January 2010, HDL made monthly processing services payments to many, if not all, of its referring physicians. HDL paid the referring physician \$20.00 each time a patient is referred for HDL testing.

475. Before it filed for bankruptcy, HDL had reported that it served 10,000 physicians. Dr. Miller, one of the first customers to switch from Berkeley to HDL, is identified on HDL's inducement checks as HDL Customer No. 041. Relators allege upon information and belief that many HDL physician customers received similar inducement checks (\$20.00 per patient referral), signed by Mallory, from HDL.

a. BlueWave Markets Singulex Inducements in Many States

476. Upon information and belief, around June 2010, BlueWave and Singulex developed a program for marketing Singulex's testing services in all states covered by Singulex and BlueWave marketing agreements.

477. Beginning in 2010, BlueWave had the exclusive right to market Singulex laboratory testing services in ever-expanding geographic areas. For example, starting in June 2010, BlueWave had the exclusive contract to market Singulex testing in North Carolina, South Carolina, Georgia, and in other areas across the United States.

478. Dr. Miller was one of many physicians in BlueWave's Singulex territory. Based on the marketing of BlueWave's representatives, Dr. Miller began to refer patients to Singulex in mid-2010.

479. Thereafter, Singulex began making significant monthly cash payments to Dr. Miller. Singulex called these payments "draw fees," which were calculated at \$10.00 each time Dr. Miller referred a patient to Singulex.

480. As stated above, Martel, one of the original BlueWave sales representatives, promoted HDL and Singulex products in Florida. Martel's partner in C&K Healthcare Consultants, Maimone, was based in New Jersey. HDL and Singulex promotional materials identifying Maimone as the sales representative were provided to a physician practice in Pennsylvania. These materials included the Singulex new customer form. Singulex provided a space on the new customer form for the sales representative to request a 1099 for the new physician.

481. Upon information and belief, the inclusion of the 1099 form request on the Singulex new customer form supports the conclusion that Singulex pays P&H fees to referring physicians with great frequency, and that Singulex marketing agents offer these P&H arrangements to prospective new customers in exchange for patient referrals.

482. Relators allege upon information and belief that many physicians in North Carolina, South Carolina, Georgia, and other states received the same promotional offer from BlueWave that was made to Dr. Miller.

483. Relators allege upon information and belief that the marketing program vetted and approved by Singulex and its former CEO Goix for potential customers in all states covered by Singulex and BlueWave marketing agreements included Singulex's offer of a \$10.00 inducement for each patient referral.

484. Upon information and belief, BlueWave's sales representatives conveyed to physicians across the country Singulex's offer to pay the physician cash remuneration of \$10.00 each time the physician referred a patient to Singulex for laboratory testing.

485. For example, Johnson, President of BlueWave, and an equity owner of Singulex, marketed Singulex products to many physicians in Alabama. Relators allege upon information and belief that Johnson and Dent (as co-founders and executives of BlueWave) would deliver only

marketing programs vetted with and approved by their client, Singulex.

486. Relators allege upon information and belief that beginning in at least June of 2010, many referring physicians throughout the United States (in addition to Dr. Miller) accepted Singulex's offer of illegal remuneration.

487. Relators allege upon information and belief that Singulex received referrals from physicians (in addition to Dr. Miller) receiving bogus "processing fees" from Singulex. Relators further allege upon information and belief that Singulex submitted claims for these tainted and unnecessary laboratory testing services to Government healthcare programs.

488. Upon information and belief, physicians in many states who referred patients to HDL and Singulex received substantial remuneration from HDL and Singulex based on national marketing schemes vetted and approved by HDL and Singulex and carried out by BlueWave. These marketing schemes resulted in HDL and Singulex submitting many claims for tainted and unnecessary laboratory testing services to Government healthcare programs.

489. Johnson, BlueWave's co-founder, has described his target physician customers as "early adopters, cutting edge physicians, draw their own blood, have the ability to draw their own blood, money hungry," smaller practices.

490. Beginning in 2010, HDL and Singulex have focused on physicians with the capacity to draw their own blood. In fact, the new customer sheets for both HDL and Singulex focused on whether the physician draws blood for patients in his or her office.

491. Relators allege upon information and belief that BlueWave targeted physicians who had the ability to have patient blood drawn in their offices (as opposed to a hospital lab or other outside laboratory) because if the patient was sent to a lab outside the doctor's office, all of the "processing" would be done there. HDL and Singulex then would have had no justification for

the bogus “processing fees” they pay to physicians to induce referrals.

2. False Records to Get False or Fraudulent Claims Paid: Singulex and HDL “Processing” Agreements with Referring Physicians

492. In 2012, Singulex entered in a written agreement with Dr. Miller titled “Agreement for Singulex Clinical Lab Cardiovascular Testing.” Relators believe that this was the first time that Singulex has put in writing its \$10.00 per patient compensation arrangement with Dr. Miller.

493. Based on statements by HDL’s CEO, Mallory, that HDL had compensation arrangements to pay referring physicians “processing fees,” Relators believe, and therefore aver, that HDL also created written agreements with referring physicians, including Dr. Miller.

494. HDL and Singulex entered into written agreements like the Singulex “Agreement for Singulex Clinical Lab Cardiovascular Testing” with referring physicians nationwide.

495. Compensation arrangements between HDL or Singulex and referring physicians purported to characterize remuneration paid by HDL and Singulex as “professional service fees” for “processing and handling” blood samples for patients referred to HDL and Singulex.

496. In reality, Relators know that many referring physicians, such as Dr. Miller, did not perform the services for which they were ostensibly responsible according to the processing agreements with HDL and/or Singulex. Even if the physicians performed the “processing” services listed, the fair market value of the services was far less than the amounts paid by Singulex (\$10.00) and by HDL (\$20.00) for each patient referred.

497. HDL, Mallory, and Singulex then submitted or caused the submission of claims to the Government for these referred patients’ laboratory tests, even if the services were unnecessary, duplicative, or worthless (*e.g.*, the patient did not fast sufficiently prior to testing), and received routinely payment worth hundreds of dollars in return.

498. Upon information and belief, at no point in time did HDL, Mallory, and/or Singulex

return such payments to the Government as an overpayment.

3. National Scope of Independent Lab Inducements for Referrals

499. LabCorp began to provide free lab services to Dr. Miller's office in early 2011, after HDL and Singulex began their nationwide schemes to offer physicians "processing fees" to induce referrals.

500. BlueWave's founder, Johnson, has highlighted the importance of in-office blood drawing services when BlueWave targets potential customers for HDL and Singulex.

501. Physicians can have the capacity to provide their patients with in-office blood drawing services either by employing a lab technician as a member of the doctor's staff - or by obtaining lab technician services paid for by an independent laboratory.

502. The new customer forms for both HDL and Singulex contained information regarding whether blood draws were performed in the doctor's office. BlueWave's, HDL's, and Singulex's focus on physicians able to draw blood in their office added to the fraudulent nature of their scheme. Government healthcare programs and private insurers reimburse laboratory testing that is medically necessary. Physicians can order only tests that are necessary for the treatment of Government healthcare program beneficiaries. It should not matter to the physician, or to the laboratory testing provider, whether the blood is drawn in the physician's office or at an outside lab.

503. The location of the blood draw was, however, critical to HDL and Singulex because these tests were marketed as a revenue stream for the referring physician. For the stream of inducements to flow from HDL and Singulex, the blood draws and processing services for HDL and Singulex tests had to be provided in the office of the doctor receiving the inducements so as to disguise the inducements as "processing" fees.

504. If the patient left the doctor's office and had blood drawn at an outside lab, that lab

would also perform the blood processing services. HDL and Singulex could not have paid the referring physician the bogus “processing” fee. Physicians either had to employ a lab technician or obtain the services of a technician from an independent lab to benefit from the HDL and Singulex inducements.

505. Relators also allege upon information and belief that independent laboratories such as LabCorp provided free laboratory-technician services and related equipment to many physicians (in addition to Dr. Miller) who referred patients to HDL and Singulex.

506. Relators allege upon information and belief that at least one purpose for independent laboratories (such as Defendant LabCorp) to provide free laboratory technician services and related equipment to physicians receiving inducements from HDL and Singulex (such as Dr. Miller) was to induce these physicians to refer patients to independent laboratories for testing in addition to the tests to be performed by HDL and Singulex.

507. To facilitate the fraud by HDL and Singulex, independent laboratories such as LabCorp provided referring physicians, including Dr. Miller, with free blood draw and processing services.

508. Relators allege upon information and belief that independent laboratories (such as Defendant LabCorp), continued to provide free phlebotomy services to physicians nationwide who referred patients to HDL and Singulex, and who, from early 2010 until at least June 2014, received cash inducements from HDL and Singulex disguised as “processing” fees. Relators further allege upon information and belief that Defendant LabCorp provided free blood processing in exchange for referrals to LabCorp.

509. HDL, Singulex, BlueWave, Dent, Johnson, and independent laboratories (such as Defendant LabCorp) conspired by engaging in illegal conduct that included, but was not limited

to, a carefully orchestrated scheme wherein HDL and Singulex offered to pay and paid to physicians throughout the United States monetary remuneration (under the guise of “processing” fees) to refer beneficiaries of Government healthcare programs and private insurance plans for laboratory testing. Independent laboratories (such as Defendant LabCorp) provided free processing services for these same referring physicians in exchange for referrals to independent laboratories (such as Defendant LabCorp) for additional, and at times duplicative, laboratory testing.

510. All of the claims for HDL, Singulex, and LabCorp testing performed for Government program beneficiaries as a result of referrals from physicians receiving inducements from HDL, Singulex, and/or LabCorp were tainted by federal AKS violations.

511. In violation of federal AKS, HDL, Singulex, and LabCorp tested beneficiaries and submitted claims to the Government healthcare programs based on illegally induced referrals. *See* Exhibit “A.”

512. Compliance with the federal AKS, and analogous state laws is a condition of payment by federal and state healthcare programs. All of the claims submitted by HDL, Singulex, and/or LabCorp based on fraudulently obtained physician referrals also violate federal FCA.

513. Relators allege upon information and belief that the business scheme by LabCorp, HDL, and Singulex resulted in systematic nationwide submissions of false claims to Government healthcare programs and private insurance plans for hundreds of millions of dollars in false claims for clinical laboratory tests tainted by anti-kickback violations, and other testing which was not medically necessary.

4. LabCorp’s, HDL’s, and Singulex’s Illegal Inducements Expose Patients to Harm

514. The scheme by LabCorp, HDL, and Singulex also exposed beneficiaries of Government healthcare programs to significant physical and economic harm.

a. Tainted Laboratory Tests Can Cause Physical Harm

515. The scheme by LabCorp, HDL, and Singulex caused real suffering for patients who were the pawns at the center of their fraudulent conduct. Exploited patients, most of whom were elderly Medicare beneficiaries, are subjected to painful and unnecessary needle sticks. Where the patient was referred for the full panel of HDL and Singulex testing, the lab required eight to nine vials of the beneficiary's blood to perform these tests. These excessive and unnecessary blood draws were especially intolerable for elderly patients.

516. Relator Webster witnessed patients complaining of lightheadedness, loss of blood, and painful needle sticks resulting from the fraudulent testing scheme.

517. The foreseeable effect of the LabCorp, HDL, and Singulex scheme, which followed from referrals initiated in response to their inducements, included prescription medications. Physicians, including Dr. Miller, unnecessarily prescribed medications to justify HDL's, Singulex's, and LabCorp's laboratory testing.

518. At the time of the initial false diagnosis of high cholesterol, nearly every one of Dr. Miller's patients was prescribed cholesterol-lowering medications in order to both support the diagnosis and also to justify the referrals to LabCorp, HDL, and Singulex.

519. For example, Dr. Miller prescribed medications for the treatment of high cholesterol to almost all patients referred to HDL, Singulex and LabCorp. These included Crestor (Rosuvastatin), which is manufactured by AstraZeneca. Crestor can have serious side effects, including a muscle problem known as rhabdomyolysis, which can lead to kidney problems, and liver damage. Patients may suffer severe muscle pain as a result of consuming the drug.

520. In addition, Dr. Miller also prescribed Simcor for nearly every patient referred to HDL and Singulex. Simcor, which is manufactured by Abbott Labs, also has serious side effects, including rhabdomyolysis. Statins like Simcor and Crestor put patients at risk for developing

serious health conditions, including, but not limited to, diabetes and memory loss.

521. Relator Webster observed patients complaining of the ill effects of these medications. In response, Dr. Miller advised the patients to continue taking medication.

522. Relators believe that physicians who were offered HDL's and Singulex's inducements, and received free services from Defendant LabCorp, initiated and maintained prescription drug therapy in part to justify referrals to HDL, Singulex, and LabCorp that will result in ongoing cash remuneration for referring physicians.

b. Tainted Laboratory Tests Cause Economic Harm to Patients

523. To further the fraudulent scheme, some physicians, including Dr. Miller, made misrepresentations to patients that they suffered from medical conditions which required the HDL, Singulex, and LabCorp testing and/or medications.

524. Patients also suffered from the negative economic impact of inaccurate diagnoses of high cholesterol used to justify HDL's, Singulex's, and LabCorp's testing. These economic harms included: unnecessary follow-up appointments with physicians to review unnecessary lab results; co-payments for unnecessary prescription drugs; costs for care related to side effects from unnecessary prescriptions; and increased insurance premiums related to increased testing, prescription usage, and related false diagnoses.

525. Relators are aware of patients who had been denied life insurance coverage because the patient was falsely diagnosed with high cholesterol.

526. There were times when the patients referred to HDL, Singulex, and/or LabCorp are not even aware that they have been given this diagnosis. Patients have contacted Dr. Miller's office to complain about the fabricated high cholesterol diagnosis. When this occurred, the office manager changed the patient record to remove the fabricated diagnosis of high cholesterol and wrote a letter to the insurance company stating that the patient was diagnosed with high cholesterol

in error.

527. In addition to prescriptions for cholesterol-lowering medications, Dr. Miller also prescribed Metanx #180, 1 tablet BID (twice a day), manufactured by PamLab, LLC. Dr. Miller told patients that Metanx improves good cholesterol. However, the FDA-approved label states that Metanx is approved only for the narrow indication of diabetic neuropathy. PamLab provided Dr. Miller with pre-printed scrip pads and samples. Dr. Miller prescribes PamLab products electronically.

528. In 2013, Metanx cost approximately \$82.56 per month.

IX. THE LABCORP, HDL, AND SINGULEX SCHEME CAUSES GOVERNMENT HEALTHCARE PROGRAMS TO PAY MILLIONS OF DOLLARS FOR UNNECESSARY, USELESS, AND EVEN HARMFUL CLINICAL LABORATORY TESTING

A. The Scheme to Submit or Cause the Submission of False Claims

529. The LabCorp, HDL, and Singulex scheme of inducing physicians to refer patients to HDL, Singulex, and LabCorp for unnecessary clinical laboratory testing included, but was not limited to, the following conduct which was ongoing from at least early 2010 through at least June 2014:

- Marketing agents, including BlueWave, Dent, and Johnson marketed the testing services of HDL and Singulex to referring physicians;
- In violation of the federal FCA and AKS, HDL offered physicians \$20 for each patient referral to HDL;
- In violation of the federal FCA and AKS, Singulex offered physicians \$10 for each patient referral to Singulex;
- In violation of the federal FCA and AKS, physicians received and accepted offers of remuneration to refer patients to HDL, Singulex, and LabCorp for testing, even

where testing was not medically necessary;

- In violation of the federal FCA and AKS, Defendant LabCorp provided referring physicians, including Dr. Miller, with remuneration in the form of phlebotomist services to physicians in exchange for referrals to LabCorp for additional (and even duplicative) testing.

530. In furtherance of the scheme, LabCorp, HDL, and Singulex conduct made or caused to be made or used false records or statements material to false or fraudulent claims, including, but not limited to:

- false records to create the appearance that cash remuneration paid by HDL and Singulex to physicians in exchange for patient referrals were for legal and appropriate professional services to be performed by referring physicians;
- false records to otherwise create the appearance that HDL's, Singulex's, and LabCorp's testing did not violate the AKS and/or was otherwise reimbursable by government healthcare programs or private healthcare insurance companies;
- false requisitions for HDL, Singulex, and LabCorp testing that were material to false or fraudulent claims submitted to Medicare, Medicaid, and other Government healthcare programs and private insurers; and
- other false records or statements, including false patient records, material to false claims submitted to Medicare, Medicaid, and other Government healthcare programs and private payors.

531. Relators believe that HDL, Singulex, and LabCorp utilized this scheme in every state across the country where HDL or Singulex paid physicians inducements to obtain fraudulent referrals of patients, including Government program beneficiaries, for laboratory testing services.

532. Relators believe that Defendant LabCorp violated the federal AKS in every state across the country where LabCorp provided phlebotomy services, including where LabCorp placed phlebotomists in physician offices.

533. Relators believe that LabCorp, HDL, and Singulex employed and/or have conspired to employ this scheme to submit false claims to federal and state healthcare programs including Medicare, Medicaid, CHAMPUS/TRICARE, and other federal healthcare programs.

534. Each and every claim that was billed to a Government healthcare program, including Medicare and/or Medicaid, for a test performed on a patient referred to HDL, Singulex, or LabCorp by a physician who received cash inducements from HDL or Singulex, and who received other remuneration from LabCorp through free phlebotomist services, violates the federal FCA.

535. Many of these testing services referred to HDL, Singulex, or LabCorp also violated the federal FCA because the tests were not medically necessary, and therefore, not covered by Government healthcare programs.

536. Relators believe that LabCorp, HDL, and Singulex employed and/or conspired to employ this scheme to submit false claims to private insurers in California and Illinois. LabCorp, HDL, and Singulex submitted claims for testing to commercial insurance companies including AETNA and Blue Cross. Examples of Blue Cross patients who were referred to HDL and Singulex for testing are provided in Exhibits B and C.

537. Each and every claim that was billed to a private insurer in California or Illinois, or for a patient located in those states, for a test performed on a patient referred to HDL, Singulex, or LabCorp by a physician who received cash inducements from HDL or Singulex, and who received other remuneration from LabCorp through free phlebotomist services, violated the CIFPA or

ILCFPA.

538. Upon information and belief, many of these testing services referred to HDL, Singulex, or LabCorp also violated the conditions of payment by private insurance companies in California or Illinois because the tests they performed and billed for were not medically necessary, and therefore, not covered.

B. Damages to Government Healthcare Programs: Millions in Reimbursements

539. HDL, Singulex, and LabCorp derived a significant portion of their earnings from reimbursements for claims submitted to government healthcare programs.

540. Relators believe that the fraudulent conduct and illegal inducements described herein to referring physicians led to exponential growth in revenues for HDL and Singulex. For example, the marketing scheme employed by BlueWave and HDL successfully catapulted HDL to the forefront of cholesterol testing market.

541. The payoff for these laboratories was rapid and dramatic.

542. For example, a single referring physician, such as Dr. Miller, referred thousands of patients to HDL, Singulex, and LabCorp each year. In 2012, Dr. Miller referred more than 200 patients per month to HDL, Singulex, and LabCorp.

543. Relators allege upon information and belief that a large percentage of patients referred for laboratory testing by physicians receiving inducements from HDL, Singulex, and LabCorp were beneficiaries of government healthcare programs, including Medicare and TriCare. For example, between August 10, 2010, and September 8, 2010, of the 200 patients referred to HDL by Dr. Miller, 98 were Medicare beneficiaries (age 65 and over). Additional patients referred by Dr. Miller were beneficiaries of TRICARE/CHAMPUS and other federal employees' health benefit programs.

1. HDL Claims Average \$1,400 Per Beneficiary, 3-4 Times a Year

544. Relators allege upon information and belief that for each government healthcare program beneficiary referred for testing by a physician receiving HDL's cash inducements, HDL submitted a claim to federal and state healthcare programs for more than \$1,400.00 per episode, and that HDL submitted claims for these expensive tests three to four times per year for every affected beneficiary of a government healthcare program.

545. Significantly, through Dr. Miller alone, HDL received 886 tainted referrals for laboratory testing between August 11, 2010, and December 30, 2010. Of the 886 claims HDL submitted for these patients, approximately 416 were for Medicare-eligible patients (aged 65 and older). More patients referred to HDL were beneficiaries of other federal healthcare programs, such as CHAMPUS/TRICARE.

546. A table summarizing some of the patients for whom claims submitted by HDL to Medicare and other Government payors is attached as Exhibit B.

2. Singulex Reimbursements Average \$300 Per Beneficiary Per Episode

547. Relators allege upon information and belief that for each government healthcare program beneficiary referred for testing by a physician receiving Singulex's cash inducements, Singulex submitted a claim to federal healthcare programs for more than \$300 per testing episode, and that Singulex submitted claims for these expensive tests three to four times per year for every affected beneficiary of a Government healthcare program.

548. Significantly, through Dr. Miller alone, Relators believe, and therefore aver, that Singulex submitted 886 tainted claims for laboratory testing between August 11, 2010, and December 30, 2010. Of the 886 claims submitted, approximately 416 were for Medicare-eligible patients (aged 65 and older). Additional patients referred to Singulex by Dr. Miller were

beneficiaries of other federal healthcare programs, such as CHAMPUS/TRICARE.

549. A table summarizing some of the patients for whom Singulex submitted claims to Medicare and other Government payors is attached as Exhibit C.

3. LabCorp Reimbursements

550. Relators also allege upon information and belief that physicians who received inducements from HDL and Singulex also referred a significant number of patients to Defendant LabCorp in exchange for free phlebotomy services related to patients referred to HDL and Singulex.

551. For example, Relators allege upon information and belief that since early 2011, Dr. Miller, a physician receiving HDL and Singulex inducements, referred at least 3,700 patients to Defendant LabCorp.

552. In addition to the 150 to 185 patients referred by Dr. Miller to HDL and Singulex each month, LabCorp also benefitted from its technician's presence in Dr. Miller's office because other patients, including those not having HDL and Singulex testing episodes, would have blood drawn and tests performed by LabCorp.

553. A significant number of the patients Dr. Miller referred to LabCorp were beneficiaries of federal healthcare programs. Relators estimate that, based on a review of patients referred to HDL and Singulex, conservatively, 47% of patients referred by Dr. Miller to LabCorp are government healthcare program beneficiaries.

554. In a study conducted in 2012, based on 2006 Medicare claims data, the most common laboratory code billed to Medicare was 36415 (venipuncture), which accounted for more than 106 million claims, or 16.1% of all Medicare Part B laboratory test claims. In 2006, Medicare paid out more than \$337 million for blood-draw services. In that same study, LabCorp was identified as one of the top two providers of lab services throughout the country.

555. Relators allege upon information and belief that the claims for venipuncture services LabCorp provided for patients referred to HDL and Singulex also involve substantial federal funds.

556. Relators allege upon information and belief that for each Government healthcare program beneficiary referred for testing by a physician receiving LabCorp's inducements of free blood draws and processing services, LabCorp submitted a claim to federal healthcare programs for both the blood draw and the LabCorp tests performed.

557. Relators also allege upon information and belief that LabCorp billed the Government and that LabCorp was reimbursed for each patient referred by a physician offered LabCorp's inducements. For example, Dr. Miller's patient, L.B., a Medicare (primary) and TRICARE (secondary) beneficiary, was referred for LabCorp testing on or about December 10, 2012. LabCorp performed the blood draw and the testing and issued a lab report on December 13, 2012. On information and belief, LabCorp later billed Medicare and/or TRICARE for the blood draw and the tests. Based on 2012 Medicare reimbursement rates for South Carolina, LabCorp received approximately \$37.43 for performing a Basic Metabolic Panel, Lipid Panel and Hepatic Function Panel, the three most common tests that LabCorp performs for Dr. Miller's patients. On this occasion, LabCorp also performed additional tests and received additional reimbursements.

558. Relators also allege upon information and belief that Defendant LabCorp submitted claims for illegally induced tests multiple times per year for many beneficiaries of Medicare and other Government healthcare programs.

559. Relators further allege upon information and belief that LabCorp's claims for venipuncture services provided on behalf of HDL and Singulex also involve substantial federal and governmental funds.

560. A table summarizing an example of the claims submitted by Defendant LabCorp to Medicare and other Government payors is attached as Exhibit D.

561. Relators allege upon information and belief that HDL, Singulex, and LabCorp have not reported to Government healthcare programs that the testing performed on patients referred by physicians receiving financial inducements from HDL, Singulex, and LabCorp should not have been covered by Government healthcare programs. In addition, Relators believe, and therefore aver, that HDL, Singulex, and LabCorp have not repaid Government healthcare programs for reimbursements for testing which were fraudulently obtained through their elaborate scheme.

562. The financial impact of the LabCorp, HDL, and Singulex fraudulent scheme on federal healthcare programs is significant.

563. As conspirators, LabCorp, HDL, and Singulex are jointly and severally liable for all damages arising out of their scheme. *See, e.g. Miller v. Holzmann*, 563 F. Supp. 2d. 54, 113 (D.D.C. 2008); *Kelso v. Fed. Crop Ins. Corp.*, 724 F. Supp. 448, 453 (E.D. Tex. 1988).

564. Relators state upon information and belief that HDL, Singulex, and LabCorp exercised the same fraudulent scheme as described herein against private insurers in California and Illinois.

565. HDL and Singulex submitted claims for payment to private insurers in California and Illinois for tests they provided only as a result of an illegal kickback provided to the referring physician.

566. Defendant LabCorp submitted claims for payment to private insurers in California and Illinois for tests it provided either as a result of the illegal kickback it provided to referring physicians in the form of free phlebotomy technician services or for services it provided as a result of HDL's and Singulex's blood draw needs.

567. Relators allege upon information and belief that HDL, Singulex, and LabCorp neither reported to any private insurance plans covering patients in California or Illinois that they performed blood draw services and/or laboratory testing on patients referred to them by physicians to whom they were providing financial inducements, nor that such claims should not have been covered by those insurance plans. In addition, Relators believe, and therefore aver, that HDL, Singulex, and LabCorp have not repaid any private insurer in California or Illinois for reimbursements for testing that were fraudulently obtained through the elaborate scheme described herein.

X. LABCORP'S CONDUCT WAS MATERIAL TO THE GOVERNMENT'S DECISION TO PAY

568. Defendant LabCorp bills government healthcare programs for clinical laboratory testing services.

569. Defendant LabCorp also provides phlebotomy services for other laboratory providers, including HDL and Singulex, both of which billed government healthcare programs for clinical laboratory testing services.

570. Government healthcare programs reimburse clinical laboratories for testing services that were medically necessary to treat the patient.

571. Compliance with the federal AKS is not only material, it is critical to the government's reimbursement decision. As a result of the PPACA amendments to the federal AKS, claims that include items or services resulting from violations of the federal AKS are, by statute, false or fraudulent claims under the federal FCA. Therefore, violations of the federal AKS, as alleged herein, are *per se* material to the Government's decision to pay a claim.

572. As alleged above, Defendant LabCorp employed unlawful schemes in violation of the federal AKS to induce physicians to refer patients to LabCorp for clinical laboratory services,

and then submitted or caused the submission of false LabCorp claims to Government healthcare programs.

573. The Government would not have paid the claims submitted by LabCorp had it known of the illegal inducements of phlebotomy services offered by LabCorp to referring physicians.

574. As alleged above, Defendant LabCorp participated and conspired with HDL, Singulex, Mallory, Bluewave, Dent, and Johnson by providing phlebotomy services for HDL and Singulex tests that were tainted by inducements that HDL, Mallory, Singulex, BlueWave, Dent, or Johnson offered to referring physicians.

575. Likewise, the Government would not have paid the claims submitted by HDL or Singulex which were similarly tainted by LabCorp's inducements of free phlebotomy services.

576. Defendant LabCorp violated the federal FCA by committing acts to further the submission of false claims to federal health care programs. By knowingly providing phlebotomy services for tests tainted by illegal inducements, LabCorp caused the submission of false HDL and Singulex claims to Government healthcare programs.

577. Defendant LabCorp's conduct is material because the federal Government would not have reimbursed either LabCorp or HDL or Singulex for any claim for laboratory services that was tainted by violations of the federal AKS.

578. Likewise, Defendant LabCorp's conduct is material because the federal Government would not have reimbursed either LabCorp or HDL or Singulex for laboratory services that were not medically necessary.

579. Defendant LabCorp knowingly presented or causing to be presented a false or fraudulent claim for payment or approval of laboratory services.

580. The named Defendant made or used false records of in support of false claims laboratory services (including false certifications of compliance with the federal AKS, and/or fraudulently documented patient charts) to get false claims paid.

581. Defendant LabCorp has deprived Government healthcare programs of the ability to uncover their fraud. LabCorp submitted requests for OIG fraud alerts (while actively pursuing and engaging in business with HDL and Singulex) through which LabCorp concealed from the government by omission its own fraudulent participation in the conduct which resulted in false LabCorp, HDL and Singulex claims. LabCorp's conduct occurred in the confines of the physician's office or a LabCorp phlebotomy service center; the Government did not know which HDL, Singulex, and LabCorp tests were being ordered, drawn, and processed for the patient referrals that were impacted by the LabCorp, HDL, and Singulex inducements.

XI. CONCLUSION

COUNT I

(UNITED STATES EX REL. LUTZ AND WEBSTER V LABCORP) Violation of the Federal False Claims Act 31 U.S.C. § 3729(a)(1)(A), (B) and (C)

582. Relators re-allege Paragraphs 1 through 581 as though fully set forth herein.

583. Defendant violated the federal FCA by submitting claims, or causing the submission of claims, for reimbursement from federal health care programs, including Medicare and Medicaid, knowing that they were ineligible for the payments demanded.

584. Claims submitted, or that were caused to be submitted, by Defendant LabCorp for clinical laboratory testing that violated the AKS constitute violations of the FCA, 31 U.S.C. § 3729(a)(1)(A).

585. Claims submitted, or that were caused to be submitted, by Defendant LabCorp for clinical laboratory testing services that were unnecessary constitute violations of the FCA, 31

U.S.C. § 3729(a)(1)(A).

586. Claims submitted, or that were caused to be submitted, by Defendant LabCorp for clinical laboratory testing services that were not appropriately provided or were useless constitute violations of the FCA, 31 U.S.C. § 3729(a)(1)(A).

587. Defendant LabCorp knowingly caused to be made or used false records or statements, material to false claims, including, but not limited to: false requisitions for laboratory testing by HDL, Singulex, or LabCorp; false certifications of medical necessity; false records of medical necessity; false processing services agreements between HDL or Singulex and referring physicians; false records related to inducements paid to referring physicians; all of which constitute violations of the federal FCA, 31 U.S.C. § 3729(a)(1)(B).

588. Defendant LabCorp, through its concerted efforts with HDL and Singulex to carry out the fraudulent scheme to bill government healthcare programs for false claims for clinical laboratory testing, conspired with HDL and Singulex to defraud the federal government by getting false or fraudulent claims (including those related to unnecessary services, as well as those claims related to referrals tainted by violations of the AKS) allowed or paid by the government in violation of the federal FCA, 31 U.S.C. § 3729(a)(1)(C).

WHEREFORE, Relators request the following relief:

A. Defendant be ordered to cease and desist from submitting and/or causing the submission of any more false claims or in any way from otherwise violating the federal False Claims Act, 31 U.S.C. §3729 *et seq.*

B. That judgment be entered in favor of the Relators and the United States and against Defendant in the amount of each and every false or fraudulent claim and so multiplied as provided by federal FCA, 31 U.S.C. § 3729(a), plus the appropriate civil penalty per claim, as provided by

31 U.S.C. §3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendant LabCorp and HDL and Singulex together with penalties for specific claims to be identified at trial after full discovery;

C. Twenty five percent 25% of the proceeds of this action to the Relators if the United States elects to intervene, and 30% if it does not;

D. That judgment be granted for the Relators and the United States and against Defendant for any costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relators in the prosecution of this suit;

E. That Defendant be enjoined from submitting, or causing to be submitted, further false claims to government healthcare programs and from attempting to collect monies for claims the Defendant has already submitted, or caused to be submitted; and

F. That Relators and the United States be entitled to any and other relief that they are entitled to, whether by law or equity.

COUNT II

(UNITED STATES EX REL. LUTZ AND WEBSTER V LABCORP) Violations of the Federal False Claims Act 31 U.S.C. § 3729(a)(1)(G)

589. Relators re-allege Paragraphs 1 through 588 as though fully set forth herein.

590. Defendant LabCorp has received overpayments by Government healthcare programs for illegally-induced and/or medically unnecessary clinical laboratory testing that must be returned.

591. Defendant LabCorp failed to report its submission of false claims for clinical laboratory testing to federal and state government healthcare programs or CMS, and Defendant

LabCorp, also failed to return payments received from government healthcare programs based upon false claims or records.

592. Defendant LabCorp was not entitled to receive payments from government healthcare programs based on claims that were false because: they violated federal Stark Laws; they contained false certifications of medical necessity; and/or they contained false certification and/or representations of compliance with federal statutes and regulations, including the federal AKS.

593. Defendant LabCorp used false records to conceal amounts that it owed government healthcare programs for payments based on unallowable claims and related charges for tainted and unnecessary clinical laboratory testing.

594. As a result of Defendant LabCorp's failure to refund amounts owed to government healthcare programs, Defendant submitted false claims in order to avoid or decrease obligations to return overpayments of state and federal funds.

595. The PPACA, 42 U.S.C. § 1128J(d), which Defendant LabCorp, and HDL and Singulex, have violated, requires that Defendant LabCorp self-report and return Government healthcare program overpayments within 60 days of identification.

596. Defendant LabCorp knowingly caused to be made or used false records or false statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States, in violation of the FCA, 31 U.S.C. § 3729(a)(1)(G).

WHEREFORE, Relators request the following relief:

A. Judgment against Defendant for three times the amount of damages the United States has sustained because of their actions, plus the appropriate civil penalty for each violation of the FCA, as provided by 31 U.S.C. §3729(a), to the extent such multiplied penalties shall fairly

compensate the United States of America for losses resulting from the various schemes undertaken by Defendant LabCorp and HDL and Singulex together with penalties for specific claims to be identified at trial after full discovery;

B. 25% of the proceeds of this action if the United States elects to intervene, and 30% if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, the costs of the audit, and other related expenses; and

D. Such other relief as the Court deems just and appropriate.

COUNT III

(CALIFORNIA, EX REL. LUTZ AND WEBSTER V LABCORP) CALIFORNIA INSURANCE FRAUDS PREVENTION ACT Cal. Ins. Code § 1871.7

597. Relators re-allege Paragraphs 1 through 596 as though fully set forth herein.

598. This is a claim for treble damages and penalties under the California Insurance Fraud Prevention Act.

599. By virtue of the acts described above, Defendant knowingly utilized a scheme by which they improperly procured “runners, cappers, steerers, and other persons” to procure patients who held private insurance contracts and against whom Defendant could file claims for payment. *See* Cal. Ins. Code § 1871.7(a).

600. Defendant knowingly presented, or caused to be presented, false or fraudulent claims to the private insurers in California, or for patients in California those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

601. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements and omitted material facts to induce the private

insurers in California, or for patients in California covered by those insurers, to approve or pay such false and fraudulent claims.

602. By virtue of the acts described above, Defendant conspired with HDL and Singulex to violate the California Insurance Fraud Prevention Act and each patient's private health insurance contract.

603. The private insurers in California, or those insurers that covered patients in California, unaware of the falsity of the records, statements, and claims made, used, presented, or caused to be presented by Defendant, paid and continue to pay the claims that are non-payable as a result of Defendant's illegal conduct.

604. Defendant knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease their respective obligations to return overpayments to these private insurance companies.

605. By reason of Defendant's acts, these private insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

606. Each claim for reimbursement that was a result of the Defendant's scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

607. The State of California is entitled to the maximum penalty of \$10,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by the Defendant.

WHEREFORE, Relators request the following relief:

A. That this Court enter judgment against the Defendant in an amount equal to three times the amount of damages that the private insurance companies have sustained because of Defendant's actions, plus a civil penalty of not less than \$5,000.00 and not more than \$10,000.00

for each violation of Cal. Ins. Code § 1871.7(a) and (b);

B. At least thirty percent (30%) and up to forty percent (40%) of the proceeds of this action to the Relators if the State of California elects to intervene, and forty percent (40%) to fifty percent (50%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and other related expenses; and

D. Such other relief as the Court deems just and appropriate.

COUNT IV

**(ILLINOIS EX REL. LUTZ AND WEBSTER V LABCORP)
ILLINOIS INSURANCE CLAIMS FRAUD PREVENTION ACT
740 Ill. Comp. Stat. § 92/1, *et seq.***

608. Relators re-allege Paragraphs 1 through 607 as though fully set forth herein.

609. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act.

610. By virtue of the acts described above, the Defendant knowingly offered and/or paid remuneration to physicians to induce the procurement of patients for Defendant's laboratory testing services for which Defendant could file claims for payment from the patients' insurers. *See* 740 Ill. Comp. Stat. § 92/5(a).

611. Defendant knowingly presented or caused to be presented false or fraudulent claims to the private insurers in Illinois, or for patients in Illinois those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

612. By virtue of the acts described above, the Defendant knowingly made, used, or caused to be made or used false records and statements and omitted material facts to induce the private insurers in Illinois, or for patients in Illinois covered by those insurers, to approve or pay

such false and fraudulent claims.

613. By virtue of the acts described above, the Defendant conspired with HDL and Singulex to violate the Illinois Insurance Claims Fraud Prevention Act and each patient's private health insurance contract.

614. The private insurers in Illinois, or those insurers that covered patients in Illinois, unaware of the falsity of the records, statements, and claims made, used, presented, or caused to be presented by the Defendant, paid and continue to pay the claims that are non-payable as a result of Defendant's illegal conduct.

615. Defendant knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease their respective obligations to return overpayments to these private insurance companies.

616. By reason of the Defendant's acts, these private insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

617. Each claim for reimbursement that was a result of the Defendant's scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

618. The State of Illinois is entitled to the maximum penalty of \$10,000.00 for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by the Defendant.

WHEREFORE, Relators request the following relief:

A. That this Court enter judgment against the Defendant in an amount equal to three times the amount of damages that the private insurance companies have sustained because of the Defendant's actions, plus a civil penalty of not less than \$5,000.00 and not more than \$10,000.00 for each violation of 740 Ill. Comp. Stat. §§ 92/5(a) and (b);

B. No less than thirty percent (30%) of the proceeds of this action to the Relators if the State of Illinois elects to intervene, and no less than forty percent (40%) if it does not;

C. Relators' attorneys' fees, litigation and investigation costs, and other related expenses; and

D. Such other relief as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, *Qui Tam* Plaintiffs hereby demand a trial by jury.

Respectfully submitted,

WINSTON & STRAWN LLP

/s/ Stacie C. Knight

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Dated: June 26, 2018

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing has been filed electronically and will be served on all counsel of record via CM/ECF. Defendant Laboratory Corporation of America Holdings has been served via its counsel, Richard S. Glaser of Parker Poe Adams & Bernstein, LLP, who has advised that he is authorized to accept service on Defendant's behalf.

The following individuals have been served via electronic mail and first-class mail:

Mitch Neumeister
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San Francisco, CA 94105
E-mail: Mitch.Neumeister@insurance.ca.gov

Jennifer Marie Zlotow, Esquire
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This the 26th day of June, 2018.

/s/ **Stacie C. Knight**

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